

University of Kentucky

Institutional Biosafety Committee (IBC) Meeting

Date: 12AUG2026
Time: 12:03PM – 1:51PM
Location: Virtual Meeting via Teams -
<https://teams.microsoft.com/meet/291258675355536?p=vw5dLo1VboqGPknJcM>

Minutes

Call to Order

The meeting was called to order by Doug Harrison at 12:03PM EST.

Attendance

IBC Members Present

Thomas Chambers (Local, Non-Affiliated Member)	Jan Smalle (Plant Containment Expert)
Doug Harrison (Chairperson)	Arthur Hunt (Plant Containment Expert)
Maria Landron (Local, Non-Affiliated Member)	Delphine Malherbe (Laboratory Staff Representative)
Brandy Nelson (Institutional Member)	Carrie Shaffer (institutional Member)
Delena Mazzetti (Biological Safety Officer)	Amelia Pinto (Institutional Member)
Cheryl Haughton (Animal Containment Expert)	

Regrets

Carol Pickett (Local, Non-Affiliated Member)
Mike Mendenhall (Local, Non-Affiliated Member)
Yadi Wu (Institutional Member)

Guests

Jeff Howell (IBC Administrative Professional II)	Jeanie Kincer (Director, Laboratory Animal Resources)
Audra Strahl (IBC Administrative Professional II)	Jillian Condrey (Attending Veterinarian Associate)
Melissa Hollifield (Animal Compliance Manager)	
Elizabeth Brooks (Administrative Support Associate I)	

Quorum

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Per the University of Kentucky Institutional Biosafety Committee By-Laws, at least 6 voting members shall constitute a quorum.

Approval of Previous Month's Meeting Minutes

[2026.07.01 IBC Meeting Minutes DRAFT.pdf](#)

The previous month's minutes were approved. Tom Chambers initiated the motion. Cheryl Haughton seconded the motion. All members present (11) voted in favor.

Old Business

None.

New Business

Review & Discussion of University of Kentucky Animal Biosafety Level 2 (ABSL-2) Biosafety Manual

[UK ABSL2 Biosafety Manual for IBC Review.pdf](#)

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The University of Kentucky Animal Biosafety Level 2 (ABSL-2) Biosafety Manual was approved pending minor modifications as listed below:

- Clarification should be made at the start of the document that the manual is intended for rodents/small animals and alternative guidance should be sought out for large animals.
- There is a typo on Page 10 under line item 7 that should be changed from "visual" to "visible."
- The term "efficacy" should be replaced with "effectiveness" where applicable (see Page 15).
- Clarification is needed regarding responsibility and provisioning of PPE by PI vs DLAR. For example, PIs should provide eye protection for their personnel and DLAR for their own personnel.
- It should be noted that cage changes are not exclusively conducted by DLAR staff.
- Hazardous service request form should be included in the appendix. Cheryl Haughton will send form template.
- In the description of closed transport of animal cages, the statement "must be provided by DLAR" implies only DLAR can provide transportation caging/carts. This should be updated to reflect that labs may use their own carts so long as they meet DLAR requirements.

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Doug Harrison initiated the motion. Tom Chambers seconded the motion. All IBC members present (11) voted in favor of the motion.

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Protocol Review

Resubmissions

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Amendments

PI: Mary Mohrin

IBC Protocol Number: IBC-24-412

Protocol Title: Molecular Mechanisms of Aging

Protocol Type: Amendment

Amendment To: Cells or tissues used in research

Applicable Guidelines & Regulations: OSHA 29 CFR 1910.1030, UK Administrative Regulation 6.3, OSHA Act of 1970 Clause 5(a)(1), NIH Guidelines Section IV-B-7, UK Administrative Regulation 6.9, NIH Guidelines Section III-E-3, NIH Guidelines Section III-D-1

Maximum Containment Level: Biological Safety Level 2 - Enhanced (BSL2+), Animal Biological Safety Level 2 (ABSL2)

Primary Reviewers: C. Haughton, D. Malherbe, T. Chambers

Brief Project Overview:

As animals age, tissues lose function and disease incidence increases. A better understanding of why we age can help us identify processes to slow or stop aging and reduce disease. The best understood way to slow aging and extend lifespan is caloric restriction. When animals are calorically restricted, a key change is increased expression and activity of a family of proteins called Sirtuins. We use the hematopoietic (blood and immune) system as a model to study tissue aging and hematopoietic stem cells (HSCs) to study stem cell aging. We aim to study the role of Sirtuins in healthy aging of the hematopoietic system as well as in hematopoietic disease states like leukemia and clonal hematopoiesis.

For our studies we will use WT (C57/BL6) mice as controls and use genetically modified mouse strains with changes in expression of Sirtuins or genes involved in hematopoietic diseases to study their effect on healthspan, lifespan, and disease development. We will also use human and mouse cells (cell lines as well as primary cells) to perform experiments in vitro to study biochemical and molecular changes that occur with age and interventions used to slow or stop aging.

To further investigate whether SIRT7 can be targeted to slow the progression of human leukemic diseases such as acute myeloid leukemia (AML), we will establish a mouse model by transplanting patient-derived bone marrow cells, with or without ex vivo SIRT7 overexpression. This experiment aims to investigate whether SIRT7 could be a potential target for treating human leukemia.

Summary of Biohazard Materials & Manipulations:

Manipulations Planned: Animal work (breeding, surgeries, etc.), Bacterial culture, Cell culture, Creation of viral vectors, DNA/RNA isolation/purification, Flow cytometry/Cell sorting, Genetics, Imaging/Microscopy, PCR/qRT-PCR, Immunohistochemistry, Histology, Proteomics, Transfection,

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Transformation, Use of Human Source Material(s), Use of viral vectors, Viral culture

Transport: Yes

Materials Transported: Animals, Biohazardous Materials

Infectious Agent(s)/Natural Host(s): Human Sourced Materials (RG2-cells, tissues, bodily fluids, organs, etc.)/ Human

Source & Nature of Inserted Nucleic Acid(s) [Gene Information/Gene Source/Gene Category/Use of Construct/Host(s)/Vector(s)]: GFP/jellyfish/reporter/tracker/overexpress GFP to track cells/primary mouse cells/Lentivirus/; Sirtuin 7/mouse/Deacetylase/overexpression/mouse primary cells/lentivirus Vector(s) [Vector Category/Vector Technical Name]: Lentivirus/pFUGw; Lentivirus/pLenti-C-mGFP; Lentivirus/pLV[Exp]-EGFP-EF1A

Cell line(s) Used [Cell Line Type/Cell Line Technical Name]: Human/human hematopoietic cells, such as CD34 (blood or bone marrow origin)/; Human/293T/; Human/OCI-AML3/; Human/OCI-AML2/; Human/BONNA-12/; Human/BJAB/; Human/MOLM-13

Animal Use: Yes

Materials introduced into Animals [Animal Host Species/Biohazardous Material/Route of Administration/Restraint/Animal Experimental Procedures/PPE/Animal Housing/Agent Shedding/Special Practices & Procedures]: Mouse/Cells - Animal, non-modified/retro orbital/anesthetized/ABSL2/lab coat, gloves, eye protection/ABSL2/No/control cells - uninfected/; Mouse/Cells - Animal, genetically modified/retro orbital/anesthetized/ABSL2/lab coat, gloves, eye protection/ABSL2/No/cells will be transduced with lenti or retro virus in vitro, then 1-3 days after they will be washed and transplanted into recipient mice/; Mouse/Cells - Human, non-modified/retro orbital/anesthetized/ABSL2/lab coat, gloves, eye protection/ABSL2/No/control cells - uninfected/; Mouse/Cells - Human, genetically modified/retro orbital/anesthetized/ABSL2/lab coat, gloves, eye protection/ABSL2/No/cells will be transduced with lentivirus in vitro or undergo electroporation, then 1-3 days after they will be washed and transplanted into recipient mice

Risk Assessment/Discussion:

Dr. Mohrin has submitted an amendment to her current IBC protocol entitled Molecular Mechanisms of Aging. In this amendment, Dr. Mohrin has added a project using human acute myeloid leukemia (AML) cells transduced to overexpress SIRT7 (and GFP control) via lentivirus. Lentivirus transduced cells will be used for xenotransplantation into mice as previously described and approved. Briefly, cells will be administered to anesthetized mice via retro-orbital injection within a BSC. 4-6 months post transplantation, mice will be euthanized and tissues collected for downstream analysis. pLenti-C-mGFP-SIRT7 and pLenti-C-mGFP-based vector is purchased from OriGene Technologies, whereas pLV[Exp]-EGFP-EF1A (control) and pLV[Exp]-EGFP-EF1A>hSIRT7 based vector from VectorBuilder. Both are 3rd generation lentiviral vectors. While they intend to purchase these vectors ready-made, Dr. Mohrin does describe the production of these new lentiviral vectors in house if they are not able to find suitable vectors commercially. In this case, they intend to use a 3rd generation packaging system using a four-plasmid packaging mix. Lentivirus is concentrated via centrifugation, which will utilize aerosol-tight safety lids. Centrifuge cups will be loaded and unloaded within a BSC. Work with lentivirus will be completed using BSL2+ containment and requires the use of lab coat, disposable gloves, and eye

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protection. All work will take place within a BSC. Dr. Mohrin is currently approved for very similar work utilizing a 2nd generation lentivirus vector. The addition of this new project does not significantly alter the biohazardous risks associated with this IBC protocol.

IBC Discussion & Vote:

The amendment to IBC-24-412 (version 50.0) was approved pending minor modifications as listed below:

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PERSONNEL: Please verify that all personnel listed on the protocol are accurate and update, if applicable.

SCIENTIFIC SUMMARY:

1. Please provide additional details regarding waste production and decontamination procedures for lentiviral work and associated downstream assays.
2. A brief statement that door signage should indicate BSL2(+) or ABSL2 when actively working with lentivirus or when administering transduced cells to animals, respectively.

Delphine Malherbe initiated the motion. Cheryl Haughton seconded the motion. All IBC members present (11) voted in favor of the motion.

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Conflicts of Interest: None

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PI: Qingzhang Zhu

IBC Protocol Number: IBC-24-493

Protocol Title: Adipocyte function in metabolism, inflammation and fibrosis during obesity

Protocol Type: Amendment

Amendment To: Cells or tissues used in research, Genetic constructs

Applicable Guidelines & Regulations: NIH Guidelines Section III-F, OSHA Act of 1970 Clause 5(a)(1), UK Administrative Regulation 6.3, UK Administrative Regulation 6.9, NIH Guidelines Section IV-B-7, NIH Guidelines Section III-D-4, NIH Guidelines Section III-F-1, NIH Guidelines Section III-F-2, NIH Guidelines Section III-E-1, OSHA 29 CFR 1910.1030

Maximum Containment Level: Biological Safety Level 2 (BSL2), Animal Biological Safety Level 1 (ABSL1), Animal Biological Safety Level 2 (ABSL2)

Primary Reviewers: C. Haughton, D. Harrison, A. Pinto

Brief Project Overview:

In the U.S., more than 40% of adults and about 20% of children are living with obesity. Obesity can lead to many serious health problems, like type 2 diabetes, liver disease, heart issues, and even cancer. Inside our bodies, there are certain fat molecules called ceramides that are more than just part of the cell's structure — they also send important signals that control how our cells behave. When people are

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obese or have diabetes, the levels of ceramides can get out of balance, which makes these health problems worse. Our research has identified a protein called PAQR4, which plays a key role in controlling ceramide levels. By influencing enzymes that make ceramides, PAQR4 helps fat tissue work better and improves how the body responds to insulin — the hormone that controls blood sugar. We're trying to better understand how PAQR4 works and how other similar proteins from the same PAQR family (PAQR1-11) might be involved in fat function, inflammation, and tissue damage. We're also looking at how these proteins affect other important cells in the body, like those in the pancreas (which make insulin), macrophages, and liver cells. To do this, we use different methods, including cell cultures and experimenting with mice to learn more about these processes and how they impact overall health. This research may help us find new ways to treat obesity and related diseases.

Summary of Biohazard Materials & Manipulations:

Manipulations Planned: Animal work (breeding, surgeries, etc.), Bacterial culture, Cell culture, DNA/RNA isolation/purification, Flow cytometry/Cell sorting, Histology, Imaging/Microscopy, Immunohistochemistry, PCR/qRT-PCR, Transfection, Transformation, Use of viral vectors, Use of Human Source Material(s), Genetics

Transport: Yes

Materials Transported: Biohazardous Materials

Infectious Agent(s)/Natural Host(s): Human Sourced Materials (RG2-cells, tissues, bodily fluids, organs, etc.)/Human

Source & Nature of Inserted Nucleic Acid(s) [Gene Information/Gene Source/Gene Category/Use of Construct/Host(s)/Vector(s)]: Adipor1/Paqr1/Mouse, human/Metabolism/Overexpression, knockdown/Expression in mammalian cells/pCDNA3.1, pCMV, pAAV, pAAVK, commercially available RNA duplexes /; Adipor2/Paqr2/Mouse, human/Metabolism/Overexpression, knockdown/Expression in mammalian cells/pCDNA3.1, pCMV, pAAV, pAAVK, commercially available RNA duplexes /; Paqr4/Mouse, human/Metabolism/Overexpression, knockdown/Expression in mammalian cells, mice/pCDNA3.1, pCMV, pEGFP, pAAV, pAAVK, commercially available RNA duplexes /; Paqr9/Mouse, human/Metabolism/Overexpression, knockdown/Expression in mammalian cells, mice/pCDNA3.1, pCMV, pEGFP, pAAV, pAAVK, commercially available RNA duplexes /; Cers2/Mouse, human/Metabolism/Overexpression, knockdown/Expression in mammalian cells, mice/pRP, pCDNA3.1, pCMV, pAAV, pAAVK, commercially available RNA duplexes /; Cers5/Mouse, human/Metabolism/Overexpression, knockdown/Expression in mammalian cells, mice/pRP, pCDNA3.1, pCMV, pAAV, pAAVK, commercially available RNA duplexes /; GFP/Synthetic/Reporter/Heterologous expression/Expression in mammalian cells, mice/pCDNA3.1, pCMV, pEGFP, pAAVK /; rtta/tetracycline-regulated transcriptional activator/Regulatory gene /Heterologous expression/Expression in mammalian cells, mice/pCDNA3.1, pAAV/; Cre/Synthetic, Cre recombinase/Regulatory gene/Heterologous expression/Expression in mammalian cells, mice/pAAV/; Cers1/Mouse, human/Metabolism/Overexpression, knockdown/Mammalian cells/pRP, pCDNA3.1, pCMV, pAAV, pAAVK, commercially available RNA duplexes /; Cers3/Mouse, human/Metabolism/Overexpression, knockdown/Mammalian cells/pRP, pCDNA3.1, pCMV, pAAV, pAAVK, commercially available RNA duplexes/; Cers4/Mouse, human/Metabolism/Overexpression, knockdown/Mammalian cells/pRP,

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pCDNA3.1, pCMV, pAAV, pAAVK, commercially available RNA duplexes/; Cers6/Mouse, human/Metabolism/Overexpression, knockdown/Mammalian cells/pRP, pCDNA3.1, pCMV, pAAV, pAAVK, commercially available RNA duplexes/; Gpnmb/Mouse, human/Metabolism/Overexpression, knockdown/Mammalian cells, mice/pCDA, pCMV, pEGFP, pAAV, pAAVK, commercially available RNA duplexes/; Paqr7/Mouse, human/Metabolism/Overexpression, knockdown/Mammalian cells, mice/pCDA, pCMV, pEGFP, pAAV, pAAVK, commercially available RNA duplexes/; Mmd/Paqr11/Mouse, human /Metabolism/Overexpression, knockdown/Mammalian cells, mice/pCDA, pCMV, pEGFP, pAAV, pAAVK, commercially available RNA duplexes/; Gltf/Mouse, human/Metabolism /Overexpression, knockdown/Mammalian cells, mice/pCDA, pCMV, pEGFP, pAAV, pAAVK, commercially available RNA duplexes/; Gpr137/Mouse, human/Metabolism/Overexpression, knockdown/Mammalian cells, mice/pCDA, pCMV, pEGFP, pAAV, pAAVK, commercially available RNA duplexes/; Smpd4/Mouse, human/Metabolism/Overexpression, knockdown/Mammalian cells, mice/pCDA, pCMV, pEGFP, pAAV, pAAVK, commercially available RNA duplexes/; Gpld1/Mouse, human/Metabolism/Overexpression, knockdown/Mammalian cells, mice/pCDA, pCMV, pEGFP, pAAV, pAAVK, commercially available RNA duplexes/; Smoc2/Mouse, human/Metabolism/Overexpression, knockdown/Mammalian cells, mice/pCDA, pCMV, pEGFP, pAAV, pAAVK, commercially available RNA duplexes

Vector(s) [Vector Category/Vector Technical Name]: Plasmid/pCMV /; Plasmid/pcDNA3.1 /; Plasmid/pEGFP/; Plasmid/pAAV/; Plasmid/pAAVK/; Plasmid/pHelper/; Plasmid/pRepCap DJ/; Plasmid/pRepCap 2/; Plasmid/pRepCap 8/; Plasmid/pRP-CMV

Cell line(s) Used [Cell Line Type/Cell Line Technical Name]: Animal/3T3-L1/; Animal/AML12/; Animal/EO771/; Human/HeLa/; Human/HEK293A/; Human/HEK293T/; Human/LX2/; Human/HepG2/; Animal/MIN6/; Animal/INS1E/; Animal/SVF/; Animal/Hepatocyte/; Animal/Hepatic stellate cell/; Animal/Adipocyte/; Animal/Macrophage/; Human/Primary human islets/; Human/HepaRG

Animal Use: Yes

Materials introduced into Animals [Animal Host Species/Biohazardous Material/Route of Administration/Restraint/Animal Experimental Procedures/PPE/Animal Housing/Agent Shedding/Special Practices & Procedures]: Mouse/Viral Vector - Adeno-Associated Virus (AAV)/intraperitoneal (IP) injection or retro-orbital (RO) injection/Anesthetized by drop isoflurane for retro-orbital injection/ABSL1/lab coat, disposable gloves, eye protection, facial mask/ABSL1/No/AAV administration will be performed once in the DLAR using the open-drop method for isoflurane anesthesia. A few drops of isoflurane will be placed on gauze in a container in a fume hood or a well-ventilated area, where the mouse will inhale the vapor until anesthetized, ensuring no direct contact with the gauze and careful monitoring to prevent overexposure. The replication-incompetent AAVs will then be administered via retro-orbital injection using a 0.5 mL syringe, lasting 3–5 seconds. The dose is 3×10^{10} - 4×10^{11} (optimum 1×10^{11}) vector genomes per animal of AAV, with a volume of 0.05-0.1 mL. Perform once. Afterward, the mouse will be monitored for eye recovery for 2 days. The cage will be marked “Do Not Change,” and a cage change will be completed after 2 days./; Mouse/Tissue - Human (ex. PDX tumor tissue)/Injected into kidney sub-capsule area/Anesthetized by isoflurane/ABSL2/lab coat, disposable gloves, eye protection, facial mask/ABSL1/No/human islets will be transplanted in mice. About 1000-1500 Islet Equivalent (IEQ) islets (1 IEQ equals the volume of a single pancreatic islet with a diameter of 150 μ m) will be resuspended in ~50 μ L of PBS and will be delivered to the kidney sub-capsule area

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(control mice will receive the same amount of saline) and the wound closed using absorbable suture and wound clip.

Risk Assessment/Discussion:

Dr. Zhu has submitted an amendment to their current IBC protocol entitled Adipocyte function in metabolism, inflammation and fibrosis during obesity. In this amendment, Dr. Zhu is updating cells/tissues used in research and genetic constructs, specifically Dr. Zhu has added new plasmid and adeno-associated virus (AAV) constructs for overexpression and knockdown in both cells and mice. Dr. Zhu's current IBC protocol includes approval for work with AAVs in cell culture and mice. The new genetic constructs will be obtained from collaborators at UT Southwestern or from commercial vendors. The new constructs are targeting genes potentially involved in sphingolipid metabolism, which may be associated obesity and diabetes. These new vectors are used in cells and mice as previously described and approved using BSL1/ABSL1 containment and requires the use of lab coat, disposable gloves, eye protection, and surgical mask. The human cell line, HepaRG, has also been added and will be used for AAV transduction as previously described and approved. The addition of these new genetic constructs does not significantly alter the biohazardous risks associated with Dr. Zhu's IBC protocol.

Jeanie Kincer left the meeting at 12:46pm during discussion of Dr. Zhu's IBC protocol

IBC Discussion & Vote:

The amendment to IBC-24-493 (version 61.0) was approved.

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Doug Harrison initiated the motion. Amelia Pinto seconded the motion. All IBC members present (11) voted in favor of the motion.

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Conflicts of Interest: None

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PI: Malinda Spry

IBC Protocol Number: IBC-25-69

Protocol Title: Biology Teaching Labs-Microbiology BIO209 and BIO309

Protocol Type: Amendment

Amendment To: Organisms used in research, Personnel

Applicable Guidelines & Regulations: UK Administrative Regulation 6.3, UK Administrative Regulation 6.9, OSHA Act of 1970 Clause 5(a)(1), NIH Guidelines Section IV-B-7

Maximum Containment Level: Biological Safety Level 2 (BSL2)

Primary Reviewers: D. Harrison, A. Hunt, C. Shaffer

Brief Project Overview:

Throughout the semester these labs use various strains of bacteria for learning purposes. They grow, test and stain these bacteria.

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Summary of Biohazard Materials & Manipulations:

Manipulations Planned: Bacterial culture, Imaging/Microscopy, Histology, Propagation of infectious agents, Use of infectious agents

Transport: No

Materials Transported: N/A

Infectious Agent(s)/Natural Host(s): *Staphylococcus epidermidis* (RG1-bacteria)/Human Skin Microbiota/; *Serratia marcescens* (RG2-bacteria)/Environmental, soil, water, plants/; *Micrococcus luteus* (RG1-bacteria)/Soil, dust, water, air/; *Enterobacter aerogenes* (RG2-bacteria)/Human and Animal GI tract/; *Proteus vulgaris* (RG2-bacteria)/GI tract humans and animals/; *Pseudomonas aeruginosa* (RG2-bacteria)/Environmental: soil, water, plants/; *Staphylococcus aureus* (RG2-bacteria)/human, livestock, companion animals, wild animals/; *Bacillus cereus* (RG2-bacteria)/Soil, vegetation, Intestinal tracts of some insects and animals/; *Enterococcus faecalis* (RG2-bacteria)/Human GI tract/; *Streptococcus agalactiae* (RG2-bacteria)/GI and Vaginal tracts of humans and bovine species/; *Streptococcus pyogenes* (RG2-bacteria)/Human skin and throat/; *Streptococcus pneumoniae* (RG2-bacteria)/Upper respiratory tract of humans/; *Klebsiella pneumoniae* (RG2-bacteria)/Human and mouse GI tract and upper respiratory tract/; *Bacillus subtilis* (RG1-bacteria)/Soil, dust, GI tract of animals/; Unknown Diagnostic Samples/Unknown Water and Soil Diagnostic Samples/; *Geobacillus stearothermophilus* (RG1-bacteria)/Soil, hot springs, ocean sediment/; *Staphylococcus saprophyticus* (RG2-bacteria)/GI tract, skin and genitourinary tracts of humans and livestock./; *Streptococcus equi* subsp. *equi* (RG2-bacteria)/Horse, donkeys, mules/; *Alcaligenes faecalis* (RG2-bacteria)/Human

Source & Nature of Inserted Nucleic Acid(s) [Gene Information/Gene Source/Gene Category/Use of Construct/Host(s)/Vector(s)]: N/A

Vector(s) [Vector Category/Vector Technical Name]: N/A

Cell line(s) Used [Cell Line Type/Cell Line Technical Name]: N/A

Animal Use: No

Materials introduced into Animals [Animal Host Species/Biohazardous Material/Route of Administration/Restraint/Animal Experimental Procedures/PPE/Animal Housing/Agent Shedding/Special Practices & Procedures]: N/A

Risk Assessment/Discussion:

Dr. Spry has submitted an amendment to the IBC protocol for BIO209 and BIO309 teaching laboratories. In this amendment, personnel have been updated and four new bacterial agents have been added - *Geobacillus stearothermophilus* (RG1), *Staphylococcus saprophyticus* (RG2), *Streptococcus equi* subsp. *equi* (RG2), and *Alcaligenes faecalis* (RG2). These organisms will be used in different assays in the teaching laboratory. The current IBC protocol already includes the use of several RG1 and RG2 microorganisms for various teaching assays. Locations, PPE required (gloves, lab coat, and goggles), and other procedures remain the same as previously approved. All work is completed using BSL2 containment. The addition of these new microorganisms does not significantly alter the biohazardous risks described in this IBC protocol.

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IBC Discussion & Vote:

The amendment to IBC-25-69 (version 36.0) was approved pending minor modifications as listed below:

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INFECTIOUS AGENTS - Infectious Agent(s) Table: Under "Route(s) of Exposure" for *Streptococcus equi*, it is stated "Does not infect humans." While *S. equi* typically does not infect humans, there are cases of rare zoonotic infections. Please update the table and risk including potential human infection and the relevant symptoms/disease.

SCIENTIFIC SUMMARY: Please acknowledge the risk of human infection with *S. equi*, although rare, is possible, particularly in immunocompromised individuals, and that students are trained accordingly.

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Doug Harrison initiated the motion. Arthur Hunt seconded the motion. All IBC members present (11) voted in favor of the motion.

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Conflicts of Interest: None

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PI: Christopher Radka

IBC Protocol Number: IBC-26-23

Protocol Title: Bacterial lipid immune modulators

Protocol Type: Amendment

Amendment To: Organisms used in research

Applicable Guidelines & Regulations: NIH Guidelines Section III-D-2, NIH Guidelines Section III-D-4, NIH Guidelines Section III-F-1, NIH Guidelines Section III-F-4, NIH Guidelines Section IV-B-7, OSHA Act of 1970 Clause 5(a)(1), OSHA 29 CFR 1910.1030, UK Administrative Regulation 6.3, UK Administrative Regulation 6.9

Maximum Containment Level: Biological Safety Level 2 (BSL2), Animal Biological Safety Level 2 (ABSL2)

Primary Reviewers: C. Haughton, C. Shaffer, B. Nelson, M. Landron

Brief Project Overview:

Lipids are chemicals that cells can use to communicate with each other. These messages can tell cells what to do, where to go, and when to grow. Bacteria growing in the body use similar lipid messages to talk to the immune system. For decades, the bacterial lipid messages have been assumed to be counter productive and tell the immune system to attack the bacteria; however, under normal conditions, beneficial bacteria in our body (like intestinal bacteria that help us digest food) are not attacked by the immune system. My research studies bacterial lipid messages that cause the immune system to leave them alone. Studying how these new messages are made and how our cells process the message could lead to better probiotic formulations, new antibiotics, and new ways to treat intestinal inflammatory disease.

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Summary of Biohazard Materials & Manipulations:

Manipulations Planned: Animal work (breeding, surgeries, etc.), Bacterial culture, Cell culture, DNA/RNA isolation/purification, Flow cytometry/Cell sorting, Genetics, Imaging/Microscopy, Immunohistochemistry, PCR/qRT-PCR, Propagation of infectious agents, Transformation, Use of Human Source Material(s), Use of infectious agents

Transport: Yes

Materials Transported: Biohazardous Materials

Infectious Agent(s)/Natural Host(s): Staphylococcus aureus (RG2-bacteria)/ Humans, animals; Staphylococcus aureus (RG2-bacteria)/ Humans, animals; Enterococcus faecalis (RG2-bacteria)/ Humans, animals; Enterococcus faecium (RG2-bacteria)/ Humans, animals; Bifidobacterium longum (RG1-bacteria)/ Humans, mammals; Bifidobacterium bifidum (RG1-bacteria)/ Humans, Mammals; Bifidobacterium breve (RG1-bacteria)/ Humans, Mammals; Alistipes finegoldii (RG1-bacteria)/ Humans, Mammals; Non-Human Primate (NHP) Materials (RG2)/ Non Human Primates; Human Sourced Materials (RG2-cells, tissues, bodily fluids, organs, etc.)/ Human; Streptococcus agalactiae (RG2-bacteria)/ Humans, mammals

Source & Nature of Inserted Nucleic Acid(s) [Gene Information/Gene Source/Gene Category/Use of Construct/Host(s)/Vector(s)]: oleate hydratase/ many bacteria/ metabolic enzyme/ expression/ E. coli K12 derivative/ pET vectors or pBluescript; oleate hydratase/ many bacteria/ metabolic enzyme/ expression/ S. aureus/ pPJ480; acyl CoA synthetase/ Homo sapiens/ metabolic enzyme/ expression/ Pichia pastoris/ pGAPZ; peroxisome proliferator activated receptor/ Homo sapiens/ regulatory gene/ expression/ E. coli K12 derivative/ pET vectors; phospholipase/ Homo sapiens/ metabolic enzyme/ expression/ Pichia pastoris/ pGAPZ; ABC transporter/ Homo sapiens/ membrane receptor/ expression/ Pichia pastoris/ pGAPZ; CD36/ Homo sapiens/ scavenger receptor/ expression/ Pichia pastoris/ pGAPZ; green fluorescent protein/ Aequorea Victoria/ tracking/ expression/ Staphylococcus aureus/ pJB38

Vector(s) [Vector Category/Vector Technical Name]: Plasmid/pET vectors; Plasmid/pJB38; Plasmid/pPJ480; Plasmid/pBluescript; Plasmid/pGAPZ

Cell line(s) Used [Cell Line Type/Cell Line Technical Name]: Animal/RAW 264.7 macrophages; Animal/Bone marrow-derived macrophages

Animal Use: Yes

Materials introduced into Animals [Animal Host Species/Biohazardous Material/Route of Administration/Restraint/Animal Experimental Procedures/PPE/Animal Housing/Agent Shedding/Special Practices & Procedures]: Mouse/ Staphylococcus aureus (RG2-bacteria)/ Intra-muscular/ Isoflurane/ ABSL2/ gloves, lab coat, eye protection/ ABSL2/ No/ Inoculations and manipulations of infected animals will take place within a BSC; Mouse/ Enterococcus faecalis (RG2-bacteria)/ oral gavage/ manual hold/ ABSL2/ gloves, lab coat, eye protection/ ABSL2/ Yes/ Inoculations and manipulations of infected animals will take place within a BSC; Mouse/ Enterococcus faecium (RG2-bacteria)/ oral gavage/ manual hold/ ABSL2/ gloves, lab coat, eye protection/ ABSL2/ Yes/ Inoculations and manipulations of infected animals will take place within a BSC; Mouse/ Alistipes finegoldii (RG1-bacteria)/ oral gavage/ manual hold/

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ABSL2/ gloves, lab coat, eye protection/ ABSL2/ Yes/ Inoculations and manipulations of infected animals will take place within a BSC; Mouse/ Bifidobacterium bifidum (RG1-bacteria)/ oral gavage/ manual hold/ ABSL2/ gloves, lab coat, eye protection/ ABSL2/ Yes/ Inoculations and manipulations of infected animals will take place within a BSC; Mouse/ Bifidobacterium breve (RG1-bacteria)/ oral gavage/ manual hold/ ABSL2/ gloves, lab coat, eye protection/ ABSL2/ Yes/ Inoculations and manipulations of infected animals will take place within a BSC; Mouse/ Bifidobacterium longum (RG1-bacteria)/ oral gavage/ manual hold/ ABSL2/ gloves, lab coat, eye protection/ ABSL2/ Yes/ Inoculations and manipulations of infected animals will take place within a BSC; Mouse/ Staphylococcus aureus (RG2-bacteria)/ subcutaneous/ scruffing and tail restraint/ ABSL2/ Gloves, lab coat, eye protection/ ABSL2/ No/ Inoculations and manipulations of infected animals will take place within a BSC

Risk Assessment/Discussion:

Dr. Radka has submitted an amendment to his current IBC protocol entitled Bacterial lipid immune modulators. In this amendment, Dr. Radka has added a new RG2 bacteria agent, *Streptococcus agalactiae*. *S. agalactiae* will be utilized for gene knockout of oleate hydratase (OhyA). These genetic modifications are currently approved using *Staphylococcus aureus* as the host. *S. agalactiae* will also be utilized for intestinal colonization model of mice. This mouse model was previously approved using *Bifidobacteria*, *Enterococci*, and *Allistipes*. All laboratory procedures remain the same as previously approved. This work will be completed using BSL2/ABSL2 containment and requires the use of lab coat, disposable gloves, and eye protection. Dr. Radka is currently approved for similar work with a variety of other RG2 bacterial agents. The addition of *S. agalactiae* does not significantly alter the biohazardous risks associated with Dr. Radka's IBC protocol.

IBC Discussion & Vote:

The amendment to IBC-26-23 (version 25.0) was approved pending minor modifications as listed below:

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ANIMAL RESEARCH - Animals with Biohazards Table: Please add an entry to the table for the new *Streptococcus* species being administered to animals.

*

Carrie Shaffer initiated the motion. Cheryl Haughton seconded the motion. All IBC members present (11) voted in favor of the motion.

*

Conflicts of Interest: None

*

New Protocols

PI: Vlad Radulescu

IBC Protocol Number: IBC-26-75

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Protocol Title: ALN-6400-002: A Phase 2, Randomized, Double-Blind Study of the Safety, Tolerability, Efficacy, and Pharmacodynamics of Multiple-Dose ALN-6400 in Adult and Adolescent Female Patients with Von Willebrand Disease (VWD) and Heavy Menstrual Bleeding (HMB)

Protocol Type: New Protocol

Amendment To: N/A

Applicable Guidelines & Regulations: NIH Guidelines Section III-C-1, OSHA Act of 1970 Clause 5(a)(1), OSHA 29 CFR 1910.1030, UK Administrative Regulation 6.3

Maximum Containment Level: Biological Safety Level 2 (BSL2)

Primary Reviewers: T. Chambers, D. Harrison, B. Nelson

Brief Project Overview:

This study is evaluating a new investigational medication called ALN-6400 for women and adolescent girls (ages 16–45) with von Willebrand disease (VWD) who experience heavy menstrual bleeding. ALN-6400 is designed to reduce production of a blood protein called plasminogen, which may help slow the breakdown of blood clots and reduce bleeding. The clinical trial will compare two dose levels of ALN-6400 in 24 participants worldwide to determine whether the treatment is safe, well tolerated, and effective at reducing menstrual blood loss and improving quality of life. Participants will receive injections every three months and will be monitored for changes in bleeding symptoms, laboratory measurements, and potential side effects. The goal of the study is to find out whether ALN-6400 can provide a longer-lasting, lower-burden treatment option for people with von Willebrand disease who struggle with heavy menstrual bleeding and other bleeding-related complications.

Summary of Biohazard Materials & Manipulations:

Manipulations Planned: Human Clinical Trial, Use of Human Source Material(s)

Transport: Yes

Materials Transported: Biohazardous Materials

Infectious Agent(s)/Natural Host(s): Human Sourced Materials (RG2-cells, tissues, bodily fluids, organs, etc.)/Human

Source & Nature of Inserted Nucleic Acid(s) [Gene Information/Gene Source/Gene Category/Use of Construct/Host(s)/Vector(s)]: siRNA for PLG (Plasminogen)/Human/Blood clot breakdown (fibrinolysis)/Reduction of the hepatic synthesis of PLG protein by interfering with PLG mRNA/Study participants/ALN-6400

Vector(s) [Vector Category/Vector Technical Name]: Naked nucleic acid/ALN-6400

Cell line(s) Used [Cell Line Type/Cell Line Technical Name]: N/A

Animal Use: No

Materials introduced into Animals [Animal Host Species/Biohazardous Material/Route of Administration/Restraint/Animal Experimental Procedures/PPE/Animal Housing/Agent Shedding/Special Practices & Procedures]: N/A

Risk Assessment/Discussion:

Dr. Radluescu has submitted a new IBC protocol for review for a clinical study entitled ALN-6400-002: A Phase 2, Randomized, Double-blind Study of the Safety, Tolerability, Efficacy, and Pharmacodynamics of

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Multiple Dose ALN-6400 in Adult and Adolescent Female Patients with Von Willebrand Disease (VWD) and Heavy Menstrual Bleeding (HMB). ALN-6400 is a synthetic small interfering RNA (siRNA) covalently linked to a GalNAc ligand that will be administered SC to suppress synthesis of the target protein, hepatic PLG protein. By reducing the expression of PLG, it is anticipated that ALN-6400 will reduce clot breakdown. ALN-6400 is manufactured by the Study Sponsor and shipped to the UK IDS Pharmacy for storage. ALN-6400 will be prepared by UK IDS Pharmacy staff according to Study Sponsor instructions and transported to the UK CCTS Outpatient Clinic for administration. They aim to enroll 2 study patients over the next 12 months. Post-administration patient samples will be obtained in the UK CCTS clinic and shipped back to the study sponsor for processing. This work will be completed using BSL2 containment and requires the use of disposable gloves, eye protection, face mask, head cover, and surgical gown.

IBC Discussion & Vote:

The protocol IBC-26-75 (version 6.0) was approved.

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Doug Harrison initiated the motion. Tom Chambers seconded the motion. All IBC members present (11) voted in favor of the motion.

*

Conflicts of Interest: None

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Renewals

PI: Maj-Linda Selenica

IBC Protocol Number: IBC-26-63

Protocol Title: Cellular and animal models of proteinopathies associated with neurodegeneration

Protocol Type: Renewal

Amendment To: N/A

Applicable Guidelines & Regulations: NIH Guidelines Section III-D-4, NIH Guidelines Section III-E-1, NIH Guidelines Section III-E-3, OSHA Act of 1970 Clause 5(a)(1), OSHA 29 CFR 1910.1030, NIH Guidelines Section IV-B-7, UK Administrative Regulation 6.3, UK Administrative Regulation 6.9

Maximum Containment Level: Animal Biological Safety Level 1 (ABSL1), Biological Safety Level 2 (BSL2)

Primary Reviewers: C. Haughton, D. Harrison, A. Pinto

Brief Project Overview:

We study proteins and stress pathways implicated in Alzheimer's disease, frontotemporal dementia, and LATE neuropathogenesis. The two hallmark proteins involved are Tau and TDP-43, both found to contribute to the pathology of a spectrum of age-related dementias. Our laboratory studies mechanistic pathways implicated in the pathology and aim to develop therapeutic strategies against TDP-43 and tau accumulation.

Summary of Biohazard Materials & Manipulations:

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Manipulations Planned: Cell culture, Animal work (breeding, surgeries, etc.), Use of Human Source Material(s), Use of viral vectors, Immunohistochemistry, Transfection

Transport: Yes

Materials Transported: Animals, Biohazardous Materials

Infectious Agent(s)/Natural Host(s): Human Sourced Materials (RG2-cells, tissues, bodily fluids, organs, etc.)/Human

Source & Nature of Inserted Nucleic Acid(s) [Gene Information/Gene Source/Gene Category/Use of Construct/Host(s)/Vector(s)]: Agmatinase (AGMAT)/Human/Enzyme/expression/mice/AAV9-pTR; AAV-PHP.eB /; Alpha synuclein/Human/Structural/expression/mice/AAV9-pTR; AAV-PHP.eB /; Arginase 1 (Arg1)/Human/Enzyme/expression/mice/AAV9-pTR; AAV-PHP.eB /; Deoxyhypusine Hydroxylase (DOHH)/Mouse/Enzyme/expression/mice/AAV9-pTR; AAV-PHP.eB /; Plasmid/; Deoxyhypusine synthase (DHS)/Mouse/Enzyme/expression/mice/AAV9-pTR; Plasmid/; Eukaryotic translation initiation factor (eIF5A)/Human/Structural/expression/mice/AAV9-pTR; AAV-PHP.eB; Plasmid/; Green Fluorescent protein (GFP)/Jellyfish/tracking/expression/mice/AAV9-pTR; AAV-PHP.eB; Plasmid/; Ornithine decarboxylase (ODC1)/Human/enzyme/expression/mice/AAV9-pTR; AAV-PHP.eB /; Ornithine decarboxylase antizyme (OAZ1)/Human/enzyme/expression/mice/AAV9-pTR; AAV-PHP.eB /; Ornithine decarboxylase antizyme inhibitor (AZIN2)/Human/enzyme/expression/mice/AAV9-pTR; AAV-PHP.eB /; Peptidyl arginine deiminase 2 (PAD2)/Human/enzyme/expression/mice/AAV9-pTR; AAV-PHP.eB; Plasmid/; Peptidyl arginine deiminase 4 (PAD4)/Human/enzyme/expression/mice/AAV9-pTR; AAV-PHP.eB; Plasmid/; Spermidine spermine N acetyl transferase 1(SSAT1)/Human/enzyme/expression/mice/AAV9-pTR; AAV-PHP.eB; Plasmid/; Spermidine synthase (SRM)/Human/enzyme/expression/mice/AAV9-pTR; AAV-PHP.eB /; Spermine Synthase (SMS)/Human/enzyme/expression/mice/AAV9-pTR; AAV-PHP.eB /; TAR DNA-binding protein 43 (TDP-43)/Human/structural/expression/mice/AAV9-pTR; AAV-PHP.eB; Plasmid/; Tau 4R2N (full length Tau)/Human/structural/expression/mice/AAV9-pTR; AAV-PHP.eB; Plasmid/; Tau C3 (C-terminal truncated Tau)/Human/structural/expression/mice/AAV9-pTR; AAV-PHP.eB; Plasmid/; GFAP-GCAMP6/mouse/GCaMP6 calcium indicator to astrocytes driven by GFAP promoter/expression/mice/AAV5-pTR/; Syn-GCAMP6/mouse/GCaMP6 calcium indicator limited to neurons as driven by Synapsin promoter/expression/mice/AAV5-pTR/; CaMKIIa-QuasAr2-mO2/mouse/neural voltage indicators for electrophysiology/expression/mice/AAV5-pTR/; GFAP-QuasAr2-mO2./mouse/astrocytic voltage indicator for electrophysiology /expression/mice/AAV5-pTR/; hSyn.iGluSnFr.WPRE.SV40/mouse/neuronal glutamate sensor driven by the synapsin promoter/expression/mice/AAV5-pTR

Vector(s) [Vector Category/Vector Technical Name]: Adeno-Associated Virus (AAV)/AAV9-pTR/; Adeno-Associated Virus (AAV)/AAV5-pTR/; Adeno-Associated Virus (AAV)/AAV-PHP.eB/; Plasmid/DOHH/; Plasmid/DHS/; Plasmid/eIF5A/; Plasmid/TDP-43/; Plasmid/PAD2/; Plasmid/PAD4/; Plasmid/SSAT1/; Plasmid/Tau/; Plasmid/GFP

Cell line(s) Used [Cell Line Type/Cell Line Technical Name]: Human/Human HeLa cell line expressing human wild type 4R0N tau (C3)/; Animal/Mouse hippocampal HT-22 expressing human mutant 4R2N-P301L tau (H11)/; Animal/Rat Microglial cell line (HAPI)/; Human/HEK293T/; Human/HEK293T expressing Tau RD P301S FRET Biosensor/; Human/HeLa/; Human/HeLa overexpressing mutated M337V TDP-43/;

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Human/HeLa overexpressing mutated Q331K TDP-43/; Human/HeLa overexpressing WT TDP-43/;
Animal/HT22/; Human/iHEK-DK/; Human/iHEK-PD/; Human/iHEK-PL/; Human/iHEK-WD/; Human/iHEK-
WT/; Human/iN2a-tau/; Human/BE(2)-M17/; Animal/N2a/; Animal/N2a-ssGT/; Human/SH-SY5Y
Animal Use: Yes

Materials introduced into Animals [Animal Host Species/Biohazardous Material/Route of
Administration/Restraint/Animal Experimental Procedures/PPE/Animal Housing/Agent Shedding/Special
Practices & Procedures]: Mouse/Viral Vector - Adeno-Associated Virus (AAV)/Injection/Anesthetized with
isoflurane/ABSL1/Disposable Gloves, Lab Coat, Safety Glasses/ABSL1/No/None

Risk Assessment/Discussion:

Dr. Selenica has submitted a renewal of her IBC protocol entitled Cellular and animal models of proteinopathies associated with neurodegeneration. Dr. Selenica's laboratory studies proteins and stress pathways implicated in Alzheimer's disease, frontotemporal dementia, and LATE neuropathogenesis, and seeks to develop therapeutic strategies against TDP-43 and tau accumulation. Towards that aim, they utilize human and mouse cell lines to investigate the mechanism behind aberrant accumulation of tau and/or TDP-43. Cells will be transfected and harvested for Western blot. Dr. Selenica's animal work involves the use of adeno-associated virus (AAV) vectors to express a variety of genes in mice via stereotaxic injection. Mice will be anesthetized for stereotaxic injections. 2-3 months after AAV administration, mice will be euthanized and brains harvested for immunohistochemistry and biochemical analyses. This work will be completed using BSL1/ABSL1 containment and requires use of lab coat, disposable gloves, eye protection, and surgical mask. The risk of parenteral inoculation during animal injections is significantly reduced in anesthetized animals secured via stereotaxic apparatus. Dr. Selenica's current IBC protocol will expire on August 22, 2026.

IBC Discussion & Vote:

The protocol renewal IBC-26-63 (version 8.0) was approved pending minor modifications as listed below:

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SCIENTIFIC SUMMARY:

1. The Infectious Agents section of the protocol indicates the use of surgical masks, which is also consistent with the PPE required in the IACUC. Please update the Scientific Summary to include surgical masks as PPE.
2. There is a description of Tau and TDP-43, but limited details about the other gene targets outlined in the protocol. Please include a brief description of each of the genes or classes of genes being manipulated and the potential effects of inadvertent AAV exposure to researchers.

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Doug Harrison initiated the motion. Amelia Pinto seconded the motion. All IBC members present (11) voted in favor of the motion.

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Conflicts of Interest: None

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PI: Gregory Graf

IBC Protocol Number: IBC-26-73

Protocol Title: Lipid metabolism in obesity and its related diseases

Protocol Type: Renewal

Amendment To: N/A

Applicable Guidelines & Regulations: NIH Guidelines Section III-D-1, NIH Guidelines Section III-D-4, NIH Guidelines Section III-E, NIH Guidelines Section III-E-1, NIH Guidelines Section III-F-1, NIH Guidelines Section III-F-2, NIH Guidelines Section III-F-8, NIH Guidelines Section IV-B-7, OSHA Act of 1970 Clause 5(a)(1), OSHA 29 CFR 1910.1030, UK Administrative Regulation 6.3, UK Administrative Regulation 6.9
Maximum Containment Level: Biological Safety Level 2 - Enhanced (BSL2+), Animal Biological Safety Level 1 (ABSL1)

Primary Reviewers: C. Haughton, M. Landron, D. Malherbe

Brief Project Overview:

Fats and cholesterol are critical for life, but can also contribute to human disease, particularly when we overconsume them or our bodies fail to utilize or excrete them properly. Many fats and cholesterol move between and within cells through molecular "pumps", channels, and lipoprotein receptors. The regulation of these transport proteins, their effects on fat and cholesterol metabolism, and their role in disease progression are poorly understood. We are focused on a series of these that include ABCG5/ABCG8, SR-BI, LDLR, and genes that may encode transporters that have yet to be described. Our goal is to understand how these are regulated at the level of the gene and protein. We are also interested in how their absence influences metabolism and the development of metabolic disease.

ABCG5 and ABCG8 are two independent proteins that form a complex that "pumps" cholesterol out of liver and into bile. Similarly, the complex is expressed in the small intestine where it pumps cholesterol (and plant sterols) out of the intestinal cells and into the lumen of the gut. ABCG5 ABCG8 is the principal mechanism opposing the accumulation of dietary sterols in blood and tissues. Accelerating the activity of this pump has the potential to confer benefit in a number of metabolic diseases that include cardiovascular disease, insulin resistance, and nonalcoholic fatty liver disease. Studies in both mice and humans are planned to evaluate the effect of genetic (mice, AAVs) and pharmacological approaches (mice & humans) can increase pump activity, as evidenced by a negative sterol balance, and improve MASLD. For the human studies, blood will be collected, and plasma markers of insulin resistance, cholesterol synthesis, and NAFLD will be measured.

Summary of Biohazard Materials & Manipulations:

Manipulations Planned: Animal work (breeding, surgeries, etc.), Bacterial culture, Cell culture, Creation of viral vectors, DNA/RNA isolation/purification, Histology, Immunohistochemistry, PCR/qRT-PCR, Propagation of infectious agents, Proteomics, Transfection, Transformation, Use of Human Source Material(s), Use of infectious agents, Use of viral vectors

Transport: Yes

Materials Transported: Animals, Biohazardous Materials

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Infectious Agent(s)/Natural Host(s): Human Sourced Materials (RG2-cells, tissues, bodily fluids, organs, etc.)/ Human; Human Sourced Materials (RG2-cells, tissues, bodily fluids, organs, etc.)/ Human; Human Sourced Materials (RG2-cells, tissues, bodily fluids, organs, etc.)/ Human

Source & Nature of Inserted Nucleic Acid(s) [Gene Information/Gene Source/Gene Category/Use of Construct/Host(s)/Vector(s)]: ABCG5/ mus musculus, C57/BL6/ ABC transporter/ ectopic expression/ human cells, mice/ pcDNA3, AAV8, Lentivirus (lentivirus ONLY in vitro); ABCG8/ mus musculus, C57/BL6/ ABC transporter/ ectopic expression ASO against ABCG8/ human cells, mice/ pcDNA3, AAV8, Lentivirus (lentivirus ONLY in vitro); ABCB4/ mus musculus, C57/BL6/ ABC transporter/ ectopic expression/ human cells, mice/ pcDNA3, AAV8; GFP/ Aequorea victoria/ Reporter/ ectopic expression/ human cells, mice/ pcDNA3, AAV8, Lentivirus (lentivirus ONLY in vitro); Cre Recombinase/ P1-like viruses P1 Phage/ enzyme/ Deletion of floxed alleles from mouse genome/ human cells, mice/ AAV8/ ; CETP (cholesterol Ester transfer protein)/ homo sapiens/ enzyme/ ectopic expression/ human cells, mice/ AAV8; ApoM (apolipoprotein)/ mus musculus, C57/BL6/ lipid transporter/ ASO against ApoM, expression via AAV/ human cells, mice/ ASO, AAV; RNF130/ Mus Musculus/ E3 ubiquitin- protein ligase/ ASO against RNF130/ None, chemical synthesis/ ASO; FGFR4/ mus musculus, C57/BL6/ Protein Kinase family/ ASO against FGFR4/ None, chemical synthesis/ ASO; PCSK9 (proprotein convertase subtilisin/kexin type 9)/ mus musculus, C57/BL6/ chaperone protein/ ectopic expression/ humans cells, mice/ AAV8; ApoA1 -m-Cherry/ mus musculus C57/BL6/ chimera/ ectopic expression/ human cells, mice/ AAV8; Cpt1a (Carnitine palmitoyltransferase 1a)/ mus musculus C57/BL6/ enzyme/ ectopic expression/ human cells, mice/ AAV8, Lentivirus (lentivirus ONLY in vitro)

Vector(s) [Vector Category/Vector Technical Name]: Plasmid/pcDNA3.1 family; Plasmid/pET28; Lentivirus/pLKO.1-puro; Naked nucleic acid/Anti-Sense Oligos

Cell line(s) Used [Cell Line Type/Cell Line Technical Name]: Animal/ CHO-K1/ ; Human/ HEK293; Animal/ CRL-1601; Animal/ WIF-B9; Human/ HepG2; Animal/ 3T3-L1; Animal/ CMT93; Human/ FHs 74; Human/ LS 174T; Animal/ MDCKII; Human/ THP1; Human/ HeLa; Human/ MCF7; Animal/ OP9; Animal/ IB10A5; Animal/ IB10H8; Animal/ IdIA7; Animal/ H2.35; Human/ Blood; Human/ Intestinal Explant

Animal Use: Yes

Materials introduced into Animals [Animal Host Species/Biohazardous Material/Route of Administration/Restraint/Animal Experimental Procedures/PPE/Animal Housing/Agent Shedding/Special Practices & Procedures]: Mouse/ Viral Vector - Adeno-Associated Virus (AAV)/ I.P. tail-vein/ tube-style restrainer/ ABSL1/ lab coat, gloves, protective eyewear/ ABSL1/ No/ n/a; Mouse/ Naked Nucleic Acid-r/sDNA/ Subcutaneous and intraperitoneal/ no special restraint required/ ABSL1/ lab coat, gloves, eye protection/ ABSL1/ No/ n/a

Risk Assessment/Discussion:

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Dr. Graf has submitted a renewal of his IBC protocol entitled Lipid metabolism in obesity and its related diseases. Dr. Graf's laboratory works to understand how regulation of transport proteins and how their absence influences metabolism and development of metabolic disease. Dr. Graf's laboratory works with human source materials, including cells, blood, and intestinal tissues, as well as adeno-associated virus (AAV) and lentivirus vectors. Cells will be cultured, transfected, and screened for compounds that may be LXX agonists. Transfected cells will also be used for pulse-chase analysis of protein synthesis and degradation. Human blood will be collected in the CCTS clinic and analyzed via ELISA for insulin and other proteins of interest. Dr. Graf's lab will also measure plasma lathosterol and analyze human lipoproteins. Intestinal tissues will be collected by CCTS biobanking staff and transported to the Graf laboratory for processing. Samples will be inactivated via Trizol for RNA isolation. AAVs, obtained from Q-biogene, will be administered to mice via IV, IP, or subcutaneous injection. Mice are restrained in a tube-style holder for tail-vein injections. AAVs will express ABCG5, ABCG8, Cre Recombinase, GFP, mCherry, ApoM, ApoA1, CETP, PCSK9, ABCB4, and Cpt1a genes and reporter genes. ASOs obtained from a commercial vendor for subcutaneous and intraperitoneal injections in mice to target ApoM, FgFR4, and RNF130. This work will be completed using BSL1/ABSL1 containment. Lastly, lentivirus vector will be obtained from VectorBuilder for transduction of cells to overexpress ABCG5, ABCG8, Cpt1a, and GFP. Lentivirus work will be completed using BSL2+ containment. Dr. Graf's current IBC protocol will expire on August 18, 2026.

IBC Discussion & Vote:

The protocol renewal IBC-26-73 (version 10.0) was approved pending minor modification as listed below:

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ANIMAL RESEARCH - Animals with Biohazards table:

1. The naked nucleic acid entry on the table states "no special restraint required." Please list the method of restraint in use, for example, manual restraint, anesthesia, etc.
2. There is an incongruency on the table where adenovirus administration to animals has been removed while the corresponding IACUC registration is still approved for adenovirus work. If adenovirus work is continuing as described in the IACUC registration, please add an entry for that work in the table.
3. Please clarify the Route(s) of Administration for AAV as "I.P," and "tail-vein," or "IV," rather than "I.P tail-vein."
4. Human derived, radio-labeled lipoproteins are being injected into animals. Please add this administration to the table.

CELL LINES - Cells in Use table: Please clarify the origin of the CRL-1601 and WIF-B9 cells. The table shows the latter as "Rattus ? / Homo sapien."

LOCATION – Research Locations: The PPE requirements listed for BSL1 work appear to be more stringent than those listed for BSL2+. Please ensure described PPE requirements are appropriate for the biosafety level of the experiments being performed.

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LOCATIONS - Biological Safety Equipment: Please review the volumes listed for Trizol and paraformaldehyde. Are these large amounts used in the biosafety cabinet or are fractions of these materials aliquoted in a chemical fume hood for use in the biosafety cabinet? List the amounts used in the biosafety cabinet at a time. The smallest amount necessary for the planned procedures should be utilized in the BSC.

SCIENTIFIC SUMMARY:

1. Briefly describe which radioisotopes are in use.
2. Please specify which disinfectants are used in each section.
3. While the functional assays for lentiviral vector are mentioned, please expand the discussion about the downstream assays being performed.
4. Describe animal restraint techniques and training for personnel. As manual restraint requires some practice, describe how only trained personnel will be permitted to perform this injection on animals.

*

Delphine Malherbe initiated the motion. Cheryl Haughton seconded the motion. All IBC members present (11) voted in favor of the motion.

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Conflicts of Interest: None

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PI: Hsin-Sheng Yang

IBC Protocol Number: IBC-26-77

Protocol Title: The role of Pdcd4 in cancer development

Protocol Type: Renewal

Amendment To: N/A

Applicable Guidelines & Regulations: NIH Guidelines Section III-F-1, NIH Guidelines Section IV-B-7, OSHA Act of 1970 Clause 5(a)(1), OSHA 29 CFR 1910.1030, UK Administrative Regulation 6.9, UK Administrative Regulation 6.3, NIH Guidelines Section III-D-1, NIH Guidelines Section III-D-2

Maximum Containment Level: Biological Safety Level 2 - Enhanced (BSL2+), Animal Biological Safety Level 1 (ABSL1)

Primary Reviewers: C. Haughton, D. Harrison, D. Malherbe

Brief Project Overview:

Programmed cell death 4 (Pdcd4) is a novel tumor suppressor. Pdcd4 has been shown to play an important role in suppression tumor growth, invasion/metastasis, and resistance to chemotherapy drugs. Thus, this study is to elucidate the molecular mechanism by which Pdcd4 regulates tumorigenesis and drug resistance. The experiments in this project will 1) determine whether Pdcd4 inhibits cell proliferation and invasion/metastasis in cultured cells and in mice; 2) determine the mechanism by which Pdcd4 inhibits tumor invasion; 3) determine the role of Pdcd4 in drug resistance

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and the underlying mechanism. The risks associated with these experiments will be that 1) transfection reagents (lipid-mediated or lentiviral-mediated) may accidentally contact with skin, 2) chemical reagents such as ethanol may accidentally contact with skin and eyes, and 3) recombinant DNA may accidentally contact with skin. To avoid these risks, personnel will always wear a lab coat, gloves, and protective glasses during experiments.

Summary of Biohazard Materials & Manipulations:

Manipulations Planned: Animal work (breeding, surgeries, etc.), Cell culture, Bacterial culture, DNA/RNA isolation/purification, Creation of viral vectors, Imaging/Microscopy, Immunohistochemistry, PCR/qRT-PCR, Transfection, Transformation, Use of infectious agents, Use of viral vectors, Use of Human Source Material(s)

Transport: Yes

Materials Transported: Biohazardous Materials

Infectious Agent(s)/Natural Host(s): Human Sourced Materials (RG2-cells, tissues, bodily fluids, organs, etc.)/human

Source & Nature of Inserted Nucleic Acid(s) [Gene Information/Gene Source/Gene Category/Use of Construct/Host(s)/Vector(s)]: Pdc4/ human/mouse/ tumor suppressor/ expression, silencing, point mutation, knockout/ human cell lines/ pLenti6/V5, pLenti6/BLOCK-iT; pSELECT-Blasti-MCS, pGL3, pSELECT-blasti-mcs, psiRNA-h7Skzeo, pcDNA3, pCMV-HA, nanoparticle; Rictor/ human/ oncogene/ expression, silencing, point mutation, knockout/ human cell lines/ pLenti6/V5. pLenti6/BLOCK-iT ; pSELECT-Blasti-MCS, pGL3, pSELECT-blasti-mcs, psiRNA-h7Skzeo, pcDNA3, pCMV-HA, eSpCas-2A-puro; PFKFB3/ Human/ glycolysis regulated protein/ Expression, point mutation, knockout/ human cell lines/ pCMV-HA, pcDNA3, eSpCas-2A-puro; PKC alpha/ human/ kinase/ expression, silencing, point mutation, knockout/ human cell lines/ pCMV-HA, pcDNA3, eSpCas-2A-puro; SOX2/ Human/ Oncogene/ expression, silencing, point mutation, knockout/ Human cell lines/ pCMV-HA, pcDNA3, eSpCas-2A-puro; SOX4/ Human/ Oncogene/ expression, silencing, point mutation, knockout/ Human cell lines/ pCMV-HA, pcDNA3, eSpCas-2A-puro; DAXX/ Human/ Oncogene/ expression, silencing, point mutation, knockout/ Human cell lines/ pCMV-HA, pcDNA3, eSpCas-2A-puro; MAGEA12/ Human/ Oncogene/ expression, silencing, point mutation, knockout/ Human cell lines/ pCMV-HA, pcDNA3, eSpCas-2A-puro; Cas9/ Streptococcus pyogenes/ DNase/ DNA knockout/ Human cell lines/ eSpCas9-2A-puro

Vector(s) [Vector Category/Vector Technical Name]: Plasmid/ pcDNA3/ ; Plasmid/ pCMV-HA/ ; Plasmid/ pSELECT-Blasti-MCS/ ; Plasmid/ pGL3/ ; Lentivirus/ pLenti6-V5-DEST/ ; Lentivirus/ pLenti6/Block-iT-DEST/ ; Plasmid/ pSELECT-blasti-mcs/ ; Plasmid/ psiRNA-h7Skzeo/ ; Plasmid/ eSpCas-2A-puro/ ; Nanoparticle/ jetPEI

Cell line(s) Used [Cell Line Type/Cell Line Technical Name]: Human/ HT29/ ; Human/ GEO/ ; Human/ LoVo/ ; Human/ RKO/ ; Human/ HCT116/ ; Human/ SW480/ ; Human/ Coca-2/ ; Human/ MCF-7/ ; Human/ D47T/ ; Human/ A549/ ; Human/ H23/ ; Animal/ JB6/ ; Human/ 293 HEK/ ; Human/ 293FT/ ; Human/ Colo 205/ ; Animal/ Pdc4 null MEF/ ; Human/ H1703/ ; Human/ LNCaP/ ; Human/ C4-2B/ ; Human/ 22Rv1/ ; Human/ MR49F/ ; Human/ C4-2R/ ; Human/ H1299/ ; Human/ H358/ ; Human/ H3255/ ;

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Human/ H460/ ; Human/ H157/ ; Human/ H2122/ ; Human/ H1650/ ; Human/ DU145/ ; Human/ H660/ ; Human/ RWPE-1/ ; Human/ LASCPC/ ; Human/ PC3

Animal Use: Yes

Materials introduced into Animals [Animal Host Species/Biohazardous Material/Route of Administration/Restraint/Animal Experimental Procedures/PPE/Animal Housing/Agent Shedding/Special Practices & Procedures]: Mouse/ Cells - Animal, genetically modified/ Subcutaneous/ isoflurane/ ABSL2/ glove, lab coat, eye protection/ ABSL1/ No/ no special procedure; Mouse/ Cells - Human, genetically modified/ Subcutaneous/ isoflurane/ ABSL2/ glove, lab coat, eye protection/ ABSL2/ No/ Use of biosafety cabinet; Mouse/ Nanoparticle-r/sNA/ IV/ isoflurane/ ABSL1/ lab coat, gloves, eye protection/ ABSL1/ No

Risk Assessment/Discussion:

Dr. Yang has submitted a renewal of IBC protocol entitled The role of Pdcd4 in cancer development. Dr. Yang's laboratory works to understand the molecular mechanism by which Pdcd4 regulates tumorigenesis and drug resistance. Dr. Yang utilizes both plasmid transfection and lentivirus transduction to overexpress or knock down wild-type and mutant Pdcd4 in lung and prostate cancer cells. Dr. Yang's laboratory will produce 3rd generation lentivirus using the ViraPower expression system and BLOCK-iT RNAi system, both from Invitrogen. Lentivirus will be concentrated via filtration, titered, and added to human tumor cells. After selection, cells will assayed for proliferation, clonogenic growth, and apoptosis. Transduced cells will also be used for subcutaneous injection into anesthetized mice. Lentivirus production and transduction will be done using BSL2+ containment and requires use of lab coat, eye protection, gloves, and surgical mask. Tumor volumes will be monitored and excised at the end of the experiment for fixation and analysis via IHC staining. Work with animals and human cells will be completed using BSL2/ABSL2 containment. Lastly, Pdcd4 plasmid nanoparticles will be administered via IV injection to anesthetized mice to evaluate its ability to suppress tumor growth. Dr. Yang's current IBC protocol will expire on September 19, 2026.

IBC Discussion & Vote:

The protocol renewal IBC-26-77 (version 9.0) was approved pending minor modifications as listed below:

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ANIMAL RESEARCH - Animals with Biohazards table:

1. The IACUC protocol 2021-3757 states "One to two million of lung cancer Cells (H23, H1299, and H1650) and prostate cancer cells (LNCaP, MR49F, and 22Rv1) will be sc. injected into the flank of mice." Please add an entry to the Animals with Biohazards table for Cells - Human, unmodified.
2. The table states that animals treated with genetically modified human cells are being housed at ABSL2. Are there any special conditions/precautions that prohibit them from ABSL1 housing?
3. The entry for Cells - Animal, genetically modified indicates "no special precautions" under Special Practices/Procedures, but the procedure biosafety level is listed as ABSL2. Is this correct?

SCIENTIFIC SUMMARY:

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1. While the potential hazards of Pdcd4 knock-down are described, there are several other constructs and materials, including TAT-RBD, being used with the potential of elevated biosafety risk. Please describe the hazards of these other constructs and describe any additional precautions in use, such as posted signage or limited access, that will be used to mitigate risk.
2. Please clarify whether animals will be anesthetized for injection TAT-RBD and Pdcd4 nanoparticles. If not, include a description of the procedures in place to reduce the risk of needle sticks.
3. The summary states that various assays and procedures are being performed, “as previously described,” with references attached to the protocol. As these affect the biological hazard risk assessment, please describe them directly in the summary instead of as a reference.
4. Please correct the typographical error in the summary that describes the use of PPE, “disposable sleeves,” instead of “disposable over-sleeves.”

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Doug Harrison initiated the motion. Delphine Malherbe seconded the motion. All IBC members present (11) voted in favor of the motion.

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Conflicts of Interest: None

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PI: Douglas Andres

IBC Protocol Number: IBC-26-82

Protocol Title: Ras Family Protein Signaling

Protocol Type: Renewal

Amendment To: N/A

Applicable Guidelines & Regulations: NIH Guidelines Section III-D-4, NIH Guidelines Section III-E-3, NIH Guidelines Section III-F-1, NIH Guidelines Section III-E-1, NIH Guidelines Section IV-B-7, OSHA 29 CFR 1910.1030, UK Administrative Regulation 6.3, UK Administrative Regulation 6.9, OSHA Act of 1970 Clause 5(a)(1)

Maximum Containment Level: Biological Safety Level 2 (BSL2), Animal Biological Safety Level 2 (ABSL2)

Primary Reviewers: C. Haughton, B. Nelson, A. Pinto

Brief Project Overview:

The Andres laboratory studies two novel families of RAS-related G-proteins and their roles in regulating cellular signaling. The first program investigates the role of the Rit and Rin proteins as regulators of pro-survival signaling pathways in neurons. The death of neurons causes or contributes to various neurodegenerative disorders including stroke, Parkinson's and Alzheimer's disease. We believe that elucidation of the mechanisms that promote neuronal survival is of fundamental importance to the development of treatment strategies to these disorders. Specifically, we have found that loss of the Rin (RIT2) G-protein improves neuronal survival and promotes recovery following brain injury. The second program investigates the molecular mechanisms of signal regulation of cardiac contraction by the novel

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RGK subfamily of GTPases (Rem, Rad and Rem2) in this process. Recent work in the Andres/Satin laboratories has identified a role for these proteins in regulating voltage-dependent Ca²⁺ channel activity in cardiac and skeletal muscle. We hypothesize that modulating Rem/Rad/Rem2 protein levels may provide a unique therapeutic approach to treating heart disease.

We utilize mammalian cell lines, isolated primary cardiac myocytes, transgenic mice, and isolated primary neurons for our studies and use recombinant DNA and lentiviral gene transfer to express genes of interest in these cells. Introduction of DNA into most of the cultured cell lines used in this work is done using standard laboratory transfection procedures. However, introduction of DNA into primary neurons and cardiomyocytes uses viral gene transfer. The viruses have been tested and are not replication competent. Appropriate procedures will be followed to minimize risk and maintain a safe working environment.

Summary of Biohazard Materials & Manipulations:

Manipulations Planned: Animal work (breeding, surgeries, etc.), Bacterial culture, Cell culture, DNA/RNA isolation/purification, Imaging/Microscopy, Immunohistochemistry, PCR/qRT-PCR, Proteomics, Transfection, Use of viral vectors, Use of Human Source Material(s)

Transport: Yes

Materials Transported: Animals, Biohazardous Materials

Infectious Agent(s)/Natural Host(s): Human Sourced Materials (RG2-cells, tissues, bodily fluids, organs, etc.)/Human

Source & Nature of Inserted Nucleic Acid(s) [Gene Information/Gene Source/Gene Category/Use of Construct/Host(s)/Vector(s)]: Rit (RIT1) GTPase/Mouse, Rat, Human/Signaling/Regulatory /Expression/Knockdown/Cells/Animals/Expression/RNAi shERWOOD0UltramiR-lentiviral shRNA/; pLTV_CMV//; phUBCmCherryP2A//; pEGFP-C1//; Rin (RIT2) GTPase/Mouse, Human/Signaling/Regulatory/Expression/Knockdown/Cells/Animals/Expression/RNAi shERWOOD0UltramiR-lentiviral shRNA/; pLTV_CMV//; pLV[Exp]-mCherry-EF1A>{3xFlag_human RIT2Q78L//; phUBCmCherryP2A//; pLV[Exp]-mCherry-EF1A>3xFLAG/3xGS/{Rat RIT2_M38A_Q78L//; pCMV-Falg-TurbID//; pKH3//; p3xFlag//; pEGFP-C1//; Rad GTPase/Mouse, Human/Regulatory/Expression/Silencing/Cells/Animals/Expression/RNAi shERWOOD0UltramiR-lentiviral shRNA/; p3xFlag//; pKH3//; pEGFP-C1//; Ca Channel CaV1.2/Mouse/Regulatory/Silencing /Cells/Animals/Expression/RNAi shERWOOD0UltramiR-lentiviral shRNA/; MAP Kinases/Human, Mouse/Regulatory/Expression/Silencing/Cells/Expression/RNAi Mission RNAi lentivirus//; pCMV//; Ras Family GTPases/Mouse/Oncogene and Signaling /Expression/Silencing /Cells/Expression/RNAi shERWOOD0UltramiR-lentiviral shRNA/; SARM1/Mouse/Scaffold and NADase/Expression/Silencing /Cells/Animals/Expression/RNAi shERWOOD0UltramiR-lentiviral shRNA/; pCMV-Myc//; pLV[Exp]-EGFP-SYN1>{human SARM1-K602E/K628E/K636E//; /pLV[Exp]-EGFP-SYN1>{human SARM1-W103A spacer 3xHA//; Toll-like receptor (TLR) oligonucleotide ligands: Let7b, CpG ODN, and ssRNA40 and scrab=mbled oligo negative controls/Synthetic oligonuceoltide(s) different squeneces- but all act to bind TLR/Receptor ligand-activation of TLR signaling /TLR Activation /Primary neuron cultures and injection into mouse/NO Vector - naked oligo /; mt-mKeima/Anthoza/Reporter/Monitor Mitophagy/Cells/Expression pHAGE-mt-Keima//; pLV-mitoDSred/Anthoza/Reporter/Monitor

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mitochondrial numbers/Cells/Expression pLTV_CMV/; LV-mCherry_mito_Grx1-roGFP2/Anthoza/Reporter/Biosensor for mitochondrial glutathione redox potential /Cells/Expression pLTV_CMV/; LV-mCherry_mito_roGFP2-Orp1/Aequorea victoria jellyfish/Reporter/Hydrogen Peroxide Biosensor /Cells/Expression pLenti6.2/; Cre recombinase/bacteriophage P1/Regulatory/Knockdown via cleavage at loxP sites /Mouse/vector pAAV.GFAP.Cre.WPRE.hGH (addgene)
 Vector(s) [Vector Category/Vector Technical Name]: Lentivirus/shERWOOD0UltramiR-lentiviral shRNA/; Plasmid/p3xFlag-CMV10/; Lentivirus/Mission shRNAi lentivirus /; Lentivirus/pHIV-dTomato/; Plasmid/pKH3/; Plasmid/pGEX4T-1/; Plasmid/pcDNA3.1/; Plasmid/pEBG/; Plasmid/pEGFP-C1/; Plasmid/pCMV-Myc/; Adenovirus/pShuttle CMV/Adtrack/; Plasmid/pET4A/; Plasmid/p3xFlag/; Adeno-Associated Virus (AAV)/AAV9/; Plasmid/pCMV-Flag-APEX2/; Plasmid/pCMV-Flag-TubID/; Lentivirus/pLV[FlexON] /; Plasmid/pET32A/; Lentivirus/pLV[Exp]-EGFP-SYN1>{human SARM1-K602E/K628E/K636E/}; Lentivirus/pLV[Exp]-EGFP-SYN1>{human SARM1-W103A spacer 3xHA/}; Adeno-Associated Virus (AAV)/AAV[Exp]-SYN1>{Mito-EGFP}:WPRE/; Lentivirus/pLV[Exp]-EF1A>{MitoTimer/}; Lentivirus/pLV[Exp]-mCherry-EF1A>{3xFlag_human RIT2Q78L/}; Lentivirus/pLV[Exp]-mCherry-EF1A>3xFLAG/3xGS/{Rat RIT2_M38A_Q78L/}; Lentivirus/pHAGE-mt-Keima/; Lentivirus/pLTV_CMV/; Lentivirus/phUBCMCherryP2A/; Adeno-Associated Virus (AAV)/pAAV.GFAP.Cre.WPRE.hGH
 Cell line(s) Used [Cell Line Type/Cell Line Technical Name]: Human/293 HEK/; Human/HeLa T4/; Animal/NIH3T3/; Animal/MIN6/; Animal/PC6/; Animal/PC12/; Animal/COS/; Animal/HIT-T15/; Human/SHSY-5Y/; Human/tSA-201/; Animal/MEF/; Animal/Hippocampal and Cortical Neurons /; Animal/Cardiac Myocyte /; Human/NCI-H2110/; Human/NCI-H1299/; Human/A549/; Animal/MC3T3-E1/; Human/SK-N-DZ/; Human/ACHN/; Human/O786/; Human/Caki2

Animal Use: Yes

Materials introduced into Animals [Animal Host Species/Biohazardous Material/Route of Administration/Restraint/Animal Experimental Procedures/PPE/Animal Housing/Agent Shedding/Special Practices & Procedures]: Mouse/Viral Vector - Adeno-Associated Virus (AAV)/stereotactic injection; Intrathecal/anesthesia/ABSL2/Lab Coat, Gloves, Eye Protection/ABSL2/No//; Mouse/Naked Nucleic Acid-r/sDNA/stereotactic, intravitreal, or intrathecal injection/Anaesthetized/ABSL1/Lab Coat, Gloves, Eye Protection/ABSL1/No/

Risk Assessment/Discussion:

Dr. Andres has submitted a renewal of his IBC protocol entitled Ras Family Protein Signaling. In Dr. Andres' lab, they seek to understand the biological function of novel families of the Ras GTP-binding protein superfamily of signaling molecules. Research in the Andres' lab can be broken down into two main research programs: 1) understanding Rit and Rin GTPases, and 2) exploring Rem and Rad-mediated regulations of Ca²⁺ voltage gated channels. This requires the construction of recombinant plasmids for transient transfection of tissue culture cells. Transfected cells will be used for a variety of downstream analysis, including GTP-activation, immunofluorescence imaging, Western blot, and others. This work will be completed using BSL2 containment and requires use of lab coat, gloves, and eye protection. Dr. Andres' laboratory also works to produce various signaling proteins via E. coli transfected with pGEX4T-1 expression vectors. Proteins will be purified via Ni-affinity chromatography. Dr. Andres' lab will also utilize adenovirus and lentivirus vectors in cell culture and adeno-associated virus (AAV) vectors in mice.

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Viral vectors will be acquired ready to use from VectorBuilder. Adenovirus and Lentivirus vectors will be used to overexpress or silence various gene targets. All work will be done using BSL2+ containment and requires use of lab coat, gloves, and eye protection. All work will be completed within a BSC. Transduced cells will be subjected to Western blot and fixation for microscopy. 3 different AAV constructs will be administered to anesthetized mice via stereotaxic or intrathecal injection. AAV work in animals will take place using BSL1/ABSL1 containment. Dr. Andres current IBC protocol will expire on October 20, 2026.

IBC Discussion & Vote:

The protocol renewal IBC-26-82 (version 9.0) was approved pending minor modifications as listed below:

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ANIMAL RESEARCH – Transgenic Animal(s) Strains: The entry in this table may be removed due to work falling under NIH Guidelines Section III-F.

ANIMAL RESEARCH - Animals with Biohazards Table: Please change the ABSL Experimental Procedures and ABSL Housing for AAV injections from ABSL2 to ABSL1.

RECOMBINANT AND/OR SYNTHETIC NUCLEIC ACID MATERIALS: Under Source/Nature of Nucleic Acid, "OPTION C: Synthetic acids that do not produce a toxin that is lethal for vertebrates at an LD50 of less than 100ng/kg body weight" would also apply and should be selected.

SCIENTIFIC SUMMARY:

1. Please review the locations described in the Scientific Summary and ensure they are congruent with those listed elsewhere in the protocol. For example, MS-514 is described as the main laboratory in BBSRB, which is inaccurate.
2. Remove references to “burn-up” biohazard bins as this would imply solid biohazardous waste is incinerated instead of autoclaved.
3. Please specify Dr. Satin’s IBC protocol number: IBC-24-423.
4. Specify that PPE will be used in all laboratory spaces as opposed to only describing their use in specific locations.

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Amelia Pinto initiated the motion. Brandy Nelson seconded the motion. All IBC members present (11) voted in favor of the motion.

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Conflicts of Interest: None

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PI: Mary Sheppard

IBC Protocol Number: IBC-26-83

Protocol Title: Mechanisms of Aortic Disease

Protocol Type: Renewal

Amendment To: N/A

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Applicable Guidelines & Regulations: NIH Guidelines Section III-F, NIH Guidelines Section III-F-1, UK Administrative Regulation 6.9, UK Administrative Regulation 6.3, OSHA 29 CFR 1910.1030, OSHA Act of 1970 Clause 5(a)(1), NIH Guidelines Section IV-B-7

Maximum Containment Level: Biological Safety Level 2 (BSL2), Animal Biological Safety Level 1 (ABSL1)

Primary Reviewers: C. Haughton, C. Shaffer, M. Landron

Brief Project Overview:

Marfan Syndrome (MFS) is a genetic connective tissue disorder which presents a variety of health issues the most serious of which are aortic aneurysms/dissections and heart valve dysfunction. Current treatments include medications prescribed to reduce blood pressure and heart rate and while these treatments have done much to improve quality of life and health of Marfan patients, surgical repair or replacement of the aorta or valves is often necessary. Our laboratory uses genetic mouse models of MFS to better understand the mechanisms of MFS-associated cardiovascular pathology with the goal of improving currently available treatments as well as identifying new ones. We use pharmacological interventions as well as genetic tools designed to reduce the expression of genes involved in the development of aortic aneurysms.

Summary of Biohazard Materials & Manipulations:

Manipulations Planned: Animal work (breeding, surgeries, etc.), Cell culture, DNA/RNA isolation/purification, Flow cytometry/Cell sorting, Histology, Imaging/Microscopy, Immunohistochemistry, PCR/qRT-PCR, Proteomics, Use of Human Source Material(s)

Transport: Yes

Materials Transported: Animals, Biohazardous Materials

Infectious Agent(s)/Natural Host(s): Human Sourced Materials (RG2-cells, tissues, bodily fluids, organs, etc.)/Human

Source & Nature of Inserted Nucleic Acid(s) [Gene Information/Gene Source/Gene Category/Use of Construct/Host(s)/Vector(s)]: ASO of AGT /synthetic /regulatory gene /knockdown /mouse/ASO injections/ osmotic pump/; N-Acetylgalactosamine (GalNAc) - conjugated ASO of AGT/synthetic /regulatory gene /knockdown /mouse/ASO injections/ osmotic pump

Vector(s) [Vector Category/Vector Technical Name]: Naked nucleic acid/antisense oligonucleotide (ASO)

Cell line(s) Used [Cell Line Type/Cell Line Technical Name]: Animal/smooth muscle cells /;

Human/smooth muscle cells /; Animal/endothelial cells/; Human/Human Umbilical Vein Endothelial Cells (HUVEC)

Animal Use: Yes

Materials introduced into Animals [Animal Host Species/Biohazardous Material/Route of Administration/Restraint/Animal Experimental Procedures/PPE/Animal Housing/Agent Shedding/Special Practices & Procedures]: Mouse/Naked Nucleic Acid-r/sDNA/subcutaneous injection/neck scruff /ABSL1/Disposable gloves, lab coat, goggles (eye protection)/ABSL1/No/Biohazardous material will be administered to animals while in a Biological Safety Cabinet.

Risk Assessment/Discussion:

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Dr. Sheppard has submitted a renewal of her IBC protocol entitled Mechanisms of Aortic Disease. Her laboratory studies Margan Syndrome (MFS), a genetic connective tissue disorder which results in a variety of health issues, the most serious of which is aortic aneurysms/dissections and heart valve disfunction. Antisense oligonucleotides (ASOs) from Ionis Pharmaceuticals or Regulus Therapeutics targeting angiotensinogen (AGT) will be administered weekly to mice for 8 weeks via intraperitoneal injection. Mice will be subjected to a variety of downstream assays and manipulations. Work with ASOs and mice will be completed using BSL1/ABSL1 containment. ASOs will also be used in cell culture to knock down expression of AGT. Work with ASOs in human cell culture will be completed using BSL2 containment. Human aortic tissues and other vascular specimens will be obtained from Pathology Core Laboratories for sectioning on a microtome or cryostat. Histological stains and immunohistochemistry will be used to identify proteins of interest, matrix, and difference cell types. This work will also be completed using BSL2 containment and requires use of lab coat, eye protection, and gloves. Dr. Sheppard's current IBC protocol will expire on October 2, 2026.

IBC Discussion & Vote:

The protocol renewal IBC-26-83 (version 8.0) was approved.

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Cheryl Haughton initiated the motion. Carrie Shaffer seconded the motion. All IBC members present (11) voted in favor of the motion.

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Conflicts of Interest: None

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PI: Guan-Yu Xiao

IBC Protocol Number: IBC-26-84

Protocol Title: A pro-metastatic secretory program activated by epithelial-to-mesenchymal transition

Protocol Type: Renewal

Amendment To: N/A

Applicable Guidelines & Regulations: NIH Guidelines Section III-D-1, NIH Guidelines Section III-D-4, NIH Guidelines Section III-E-1, NIH Guidelines Section III-F, NIH Guidelines Section III-F-1, NIH Guidelines Section III-F-3, NIH Guidelines Section IV-B-7, OSHA Act of 1970 Clause 5(a)(1), OSHA 29 CFR 1910.1030, UK Administrative Regulation 6.3, UK Administrative Regulation 6.9

Maximum Containment Level: Biological Safety Level 2 - Enhanced (BSL2+), Animal Biological Safety Level 2 (ABSL2)

Brief Project Overview:

Exocytosis, also known as secretory trafficking, involves the movement of molecules to intracellular destinations and the plasma membrane for secretion. Proteins destined for secretion are synthesized in the endoplasmic reticulum and transferred to the Golgi apparatus, where cargos are packaged into secretory vesicles that are transported to the plasma membrane through post-Golgi traffic. This

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machinery is tightly orchestrated to organize the cell microenvironment that regulates cell motility and immunity. Aberrant secretory trafficking leads to diverse diseases, including cancers.

Epithelial-to-mesenchymal transition (EMT) underlies enhanced cell motility and immunosuppression, thereby driving cancer metastasis in epithelial malignancies. However, the way in which EMT orchestrates disparate biological processes remains unclear. We recently found that EMT activates a secretory program in the K-RAS and p53 mutant human lung cancer that enhances cell migration and invasion, and establishes an immunosuppressive tumor microenvironment to promote cancer progression. Thus, we would like to study the functions of mediators in the EMT-driven secretory program and test whether genetically or pharmaceutically inhibiting the specific mediators could prevent cancer progression.

Summary of Biohazard Materials & Manipulations:

Manipulations Planned: Animal work (breeding, surgeries, etc.), Bacterial culture, Cell culture, DNA/RNA isolation/purification, Flow cytometry/Cell sorting, Genetics, Histology, Imaging/Microscopy, Immunohistochemistry, PCR/qRT-PCR, Proteomics, Transfection, Transformation, Use of viral vectors, Creation of viral vectors, Use of Human Source Material(s)

Transport: Yes

Materials Transported: Animals, Biohazardous Materials

Infectious Agent(s)/Natural Host(s): Human Sourced Materials (RG2-cells, tissues, bodily fluids, organs, etc.)/Human

Source & Nature of Inserted Nucleic Acid(s) [Gene Information/Gene Source/Gene Category/Use of Construct/Host(s)/Vector(s)]: REEP2/Mus musculus Homo sapiens/Scaffold protein/Expression Knockdown/Human cell lines; Murine cell lines; Mus musculus/EGFP-C1 plasmid; Lentiviral Vector: SMARTvector Lentiviral shRNA; EGFP/Aequorea victoria/Tracking genes/Expression/Human cell lines; Murine cell lines/EGFP-C1 plasmid; SEC24D/Homo sapiens/Scaffold protein/Expression/Human cell lines; Murine cell lines/pmCherry-C1 plasmid; Golgi targeting sequence/Homo sapiens/Scaffold protein/Expression/Human cell lines; Murine cell lines/pmTurquoise2-N1 plasmid; Cre recombinase/Bacteriophage P1/Enzymatic protein/Expression/Mice/Lentiviral Vector: Lenti-Cre Vector(s) [Vector Category/Vector Technical Name]: Plasmid/pmCherry-C1 plasmid; Plasmid/pmTurquoise2-N1 plasmid; Plasmid/EGFP C1 plasmid; Lentivirus/Lenti-Cre (Plasmid #198712); Lentivirus/SMARTvector Lentiviral shRNA

Cell line(s) Used [Cell Line Type/Cell Line Technical Name]: Human/H322; Human/HCC827; Human/H1299; Animal/393P_Vec; Animal/393P_ZEB1; Animal/393P; Animal/344SQ; Animal/307P
Animal Use: Yes

Materials introduced into Animals [Animal Host Species/Biohazardous Material/Route of Administration/Restraint/Animal Experimental Procedures/PPE/Animal Housing/Agent Shedding/Special Practices & Procedures]: Mouse/Cells - Animal, genetically modified/subcutaneous or intrathoracic injection/anesthesia/ABSL1/Eye Protection, Gloves, Lab Coat/ABSL1/No/Biosafety Level 1 facilities, equipment, and operational practices for work involving infectious or potentially infectious materials, animals, or cultures.; Mouse/Viral Vector - Lentivirus/Intratracheal delivery/anesthesia/ABSL2/Eye Protection, Gloves, Lab Coat, Respiratory Protection, Boots or Shoe Covers, Surgical Mask,

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Coverall/Smock, Head Cover/ABSL2/Yes/Biosafety Level 2+ facilities, equipment, and operational practices for work involving infectious or potentially infectious materials, animals, or cultures. NO open bench work. All procedures must be conducted in a biological safety cabinet (BSC). The use of needles, syringes, and other sharp objects should be strictly limited. The animals will be moved from ABSL2 housing to ABSL1 housing 72 hours after administration of lentivirus.

Risk Assessment/Discussion:

Dr. Xiao has submitted a renewal of their IBC protocol entitled A pro-metastatic secretory program activated by epithelial-to-mesenchymal transition. Dr. Xiao's laboratory seeks to understand how aberrant secretory trafficking leads to a variety of diseases, including cancer. They will create murine REEP2 knockout cell lines using 2nd generation shRNA lentiviral vectors obtained from Horizon. Lentivirus will be generated using 2nd generation packaging plasmids and filtered to transduce murine cells. The transgenes are potential tumor metastasis drivers or tumor suppressor genes, and Dr. Xiao acknowledges the potential increase in cancer risk should personnel be exposed. Lentiviral work will be completed using BSL2+ containment. All manipulations will be completed within a BSC and require disposable gown or dedicated lab coat, gloves, and eye protection. Stably transduced cells will be administered anesthetized mice via intra-thoracic injection to generate lung tumors. Tumor burden will be monitored via microCT weekly until euthanasia. Necropsies will be performed to measure tumors and quantify metastases. They will also use a lentivirus expressing Cre to be delivered intratracheally to anesthetized mice within a BSC. Mice will be housed at ABSL2 containment for 72 hours post administration, after which they will be moved to ABSL1 housing. Replication competent virus (RCV) testing will be completed on all lentivirus vector, including shRNA and Cre lentivirus, prior to its use (or use of transduced cells) in animals. Dr. Xiao's current IBC protocol will expire on September 14, 2026.

IBC Discussion & Vote:

The protocol renewal IBC-26-84 (version 12.0) was approved pending minor modifications as listed below:

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ANIMAL RESEARCH - Animals with Biohazards Table: the PPE listed for lentivirus work has some redundant language: "lab coat and coverall/smock"; "respiratory protection and surgical mask." Please update with the specific PPE that will be used for the procedure, ensuring congruency with PPE requirements elsewhere in the protocol.

LOCATIONS - Biological Safety Cabinet Table: Please update the certification expiration dates for the units in HKRB 550J.

SCIENTIFIC SUMMARY:

1. There is a note about PPE use with lentiviruses that reads "(consider double-gloving)" that is ambiguous. Clearly state that double-gloving will be used.
2. It is unclear how unfixed biohazardous material will be transported. Please provide a brief description of transportation of biohazardous materials between laboratory locations. If biohazardous materials are fixed prior to transport, please clearly describe how this is done.

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3. Please remove “without restrain” from the procedural description of the subcutaneous model as the use of anesthesia functions as a restraint method.
4. For intratracheal administration is there the option to utilize a blunt tip for administration? The "Exel Safelet IV catheter" described in the Scientific Summary appears to be a very sharp needle.

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Tom Chambers initiated the motion. Brandy Nelson seconded the motion. All IBC members present (11) voted in favor of the motion.

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Conflicts of Interest: None

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PI: Michael Flythe

IBC Protocol Number: IBC-26-86

Protocol Title: Bacterial Survival in Plant Biomass

Protocol Type: Renewal

Amendment To: N/A

Applicable Guidelines & Regulations: NIH Guidelines Section IV-B-7, OSHA Act of 1970 Clause 5(a)(1), OSHA 29 CFR 1910.1030, UK Administrative Regulation 6.3, UK Administrative Regulation 6.9

Maximum Containment Level: Biological Safety Level 2 (BSL2)

Primary Reviewers: C. Shaffer, M. Landron, J. Smalle

Brief Project Overview:

The purpose of the research is to determine the susceptibility of (environmental) mastitis-causing bacteria to hemp hurd and other ground plant materials (treatment materials). Antibiotics have become less effective due to the rise in antibiotic resistant bacteria. We look for alternatives to antibiotics in plants, and there has been promising preliminary work done in hemp and other plants (treatment material). We are looking to test the susceptibility of mastitis-causing pathogens to ground plant materials using a bedding additive approach, where we will expose pathogens to equal parts treatment and standard bedding material to elucidate any inhibitory properties that may be present in the treatment material in liquid culture of volumes less than 10 mL. The following pathogens will be used in the described experiments: *M. haemolytica*, *P. aeruginosa*, *S. aureus*, *K. pneumoniae*, *S. dysgalactiae*, *S. uberis*, *E. faecalis*, *E. coli* o15:h7.

Summary of Biohazard Materials & Manipulations:

M Manipulations Planned: Bacterial culture, Use of infectious agents

Transport: No

Materials Transported: N/A

Infectious Agent(s)/Natural Host(s): *Escherichia coli* (entero-hemorrhagic) RG2 Bacteria/Humans, animals/; *Pseudomonas aeruginosa* (RG2-bacteria)/Humans, animals, plants/; *Staphylococcus aureus* (RG2-bacteria)/Humans, animals/; *Enterococcus faecalis* (RG2-bacteria)/Humans, animals/;

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Fusobacterium necrophorum (RG2-bacteria)/Humans, animals (including horses, cattle, sheep, goats, pigs, and fowl)/; Klebsiella pneumoniae (RG2-bacteria)/Humans, animals/; Mannheimia haemolytica (RG1-bacteria)/Bovine/; Streptococcus uberis (RG1-bacteria)/Humans, mammals/; Streptococcus agalactiae (RG2-bacteria)/Humans, animals (particularly cattle)

Source & Nature of Inserted Nucleic Acid(s) [Gene Information/Gene Source/Gene Category/Use of Construct/Host(s)/Vector(s)]: N/A

Vector(s) [Vector Category/Vector Technical Name]: N/A

Cell line(s) Used [Cell Line Type/Cell Line Technical Name]: N/A

Animal Use: No

Materials introduced into Animals [Animal Host Species/Biohazardous Material/Route of Administration/Restraint/Animal Experimental Procedures/PPE/Animal Housing/Agent Shedding/Special Practices & Procedures]: N/A

Risk Assessment/Discussion:

Dr. Flythe has submitted a renewal of his IBC protocol entitled Bacterial Survival in Plant Biomass. In this IBC protocol, Dr. Flythe describes two experiments that utilize different RG2 bacterial agents to examine the effectiveness of various antibiotic alternatives, including hemp and other plant extracts. The following bacterial pathogens are utilized in this IBC protocol, Mannheimia haemolytica (RG1), Pseudomonas aeruginosa (RG2), Staphylococcus aureus (RG2), Klebsiella pneumoniae (RG2), Streptococcus agalactiae (RG2), Streptococcus uberis (RG1), Enterococcus faecalis (RG2), Escherichia coli (RG2), and Fusobacterium necrophorum (RG2). In the first project, they aim to test the susceptibility of mastitis causing pathogens to ground plant materials using a bedding additive approach where pathogens will be exposed to treatment and standard bedding. In the second project, F. necrophorum will be exposed to CBD and other terpenoids extracted from hemp to determine their inhibitory properties. Bacteria are cultured within a Class II BSC, except F. necrophorum which is transferred and propagated within a sealed anaerobic glove box. All work with bacterial pathogens will be completed using BSL2 containment and requires the use of lab coat, gloves, and eye protection. Dr. Flythe's current IBC protocol will expire on September 4, 2026.

Melissa Hollifield left the meeting at 1:41pm during discussion of Dr. Flythe's IBC protocol

IBC Discussion & Vote:

The protocol renewal IBC-26-86 (version 8.0) was approved pending minor modifications as listed below:

*

DISINFECTANTS, EMERGENCY RESPONSE, TRANSPORT, WASTE – Emergency Response: Please select "Yes" under the procedure outlining the spill response or provide details of the alternative spill response procedures your lab will use.

SCIENTIFIC SUMMARY: Please provide justification for why the bacteria are stored in glass vials in the freezer. Plastic vials with a screw cap would be less likely to cause injury should they break.

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Jan Smalle initiated the motion. Carrie Shaffer seconded the motion. All IBC members present (11) voted in favor of the motion.

*

Conflicts of Interest: None

Incident Review

None.

Protocol Issued Registration Numbers

Protocols issued registration numbers, including minor amendments. These protocols are exempt from IBC review and are registered with the UK Biological Safety Officer (BSO).

Norian, Lyse, Translational Immuno-oncology studies, Amendment, BSO, IBC-25-137 (v.25.0), 8/12/2026

Alam, M. Ashfaque, The Effect of Microbiome and Metabolome on Intestinal Epithelial Cells., Amendment, BSO, IBC-24-347 (v.30.0), 8/11/2026

Gordon, Scott, Lipoprotein Physiology in Metabolism and Atherosclerosis, Amendment, BSO, IBC-24-453 (v.43.0), 8/6/2026

Ubil, Eric, PTP1b Inhibition Restores the Innate Anti-tumor Response During Chemotherapy, Amendment, BSO, IBC-24-446 (v.36.0), 8/6/2026

Pinto, Amelia, Risk Group 2 Virus Protocol, Amendment, BSO, IBC-24-83 (v.76.0), 8/6/2026

Klotz, James, B23-4329: Effect of ergot alkaloids on cellular receptors and subsequent signaling, Amendment, BSO, IBC-24-139 (v.15.0), 8/5/2026

Blackburn, Jessica, Identifying mechanisms of cancer progression using lentiviral infected human cell lines, Amendment, BSO, IBC-25-60 (v.24.0), 8/5/2026

Flythe, Michael, The ecology and physiology of anaerobic bacteria in grazing animals, Amendment, BSO, IBC-26-10 (v.18.0), 8/5/2026

Weisleder, Noah, Modifying gene expression in vitro and in vivo, Amendment, BSO, IBC-24-499 (v.76.0), 8/4/2026

Feola, David, Mechanisms of Alternative Macrophage Activation, Amendment, BSO, IBC-26-29 (v.20.0), 7/31/2026

Galperin, Emilia, Regulation of MAPK activity by EGF receptor endocytosis, Amendment, BSO, IBC-25-123 (v.18.0), 7/31/2026

Tackenberg, Michael C., Genetic, molecular, and environmental determinants of circadian period length and output phase., Amendment, BSO, IBC-25-130 (v.38.0), 7/31/2026

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Evers, B. Mark, Signaling pathways in the regulation of colon cancer metastasis, intestine differentiation, gut endocrine cell secretion, hepatic lipogenesis and pancreatic acinar cell aging., Amendment, BSO, IBC-24-472 (v.52.0), 7/30/2026

Hao, Zhonglin, 23-LUN-133-LB (LB2102-1001): A First in Human Dose Escalation and Cohort Expansion Study of DLL3-directed Chimeric Antigen Receptor T-cells in Subjects with Extensive Stage Small Cell Lung Cancer., Amendment, BSO, IBC-26-43 (v.14.0), 7/28/2026

Papazoglou, Ioannis, Neuronal response to hypoglycemia, Amendment, BSO, IBC-24-35 (v.63.0), 7/27/2026

Mishra, Ila, Small peptide hormones in metabolic disorders, Amendment, BSO, IBC-24-89 (v.54.0), 7/27/2026

Bruntz, Ronald, B23-4084: Research Mass Spectrometry and Proteomics Core Lab, Amendment, BSO, IBC-24-24 (v.13.0), 7/27/2026

Temel, Ryan, Knockdown and overexpression of genes in mice and nonhuman primates using antisense oligonucleotides (ASO), Amendment, BSO, IBC-26-07 (v.22.0), 7/27/2026

Chakravarti, Ritu, Immune Mechanisms of Autoimmune Diseases, Amendment, BSO, IBC-24-522 (v.51.0), 7/27/2026

Firestein, Bonnie, Regulation of Dendritic Morphology and Function by Cypin, the Main Guanine Deaminase, and Other Proteins, Amendment, BSO, IBC-25-104 (v.29.0), 7/24/2026

Radka, Christopher, Bacterial lipid immune modulators, Amendment, BSO, IBC-26-23 (v.16.0), 7/22/2026

Shoemaker, Robin, Biosafety protocol for Shoemaker lab, Closure, BSO, IBC-24-434 (v.21.0), 7/21/2026

Lima, Florence, Metabolic Bone Disease Registry, Renewal, BSO, IBC-26-61 (v.6.0), 7/20/2026

Kuhs, Krystle, B24-4382: Kentucky Research Registry and Specimen Bank, Amendment, BSO, IBC-24-136 (v.17.0), 7/20/2026

Richards, Christopher, HkRB Microscopy Core Facility, Amendment, BSO, IBC-25-161 (v.16.0), 7/20/2026

Ubil, Eric, PTP1b Inhibition Restores the Innate Anti-tumor Response During Chemotherapy, Amendment, BSO, IBC-24-446 (v.26.0), 7/16/2026

Samaan, Michael, Exercise Science Biosafety Protocol, Renewal, BSO, IBC-26-68 (v.8.0), 7/15/2026

Yamasaki, Tritia, Synuclein seeding activity as a biomarker in Parkinson Disease, Amendment, BSO, IBC-24-477 (v.43.0), 7/14/2026

Gonzalez Duque, Octavio, Effect of oral bacteria on innate epithelial responses, Amendment, BSO, IBC-25-70 (v.28.0), 7/13/2026

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Fong, Ka Wing, Understanding the mechanisms underlying advanced prostate cancer and finding novel therapies, Amendment, BSO, IBC-24-385 (v.73.0), 7/10/2026

Xiao, Xu, Intracellular Cholesterol transport in metabolic diseases, Amendment, BSO, IBC-24-469 (v.53.0), 7/10/2026

Plattner, Rina, Role of Abl Family Kinases in Solid Tumors, Amendment, BSO, IBC-24-474 (v.45.0), 7/10/2026

Shaddox, Luciana, 1. Analysis of Host-Biofilm Interactions: A Novel Polymicrobial model 2: Evaluation of different risk factors on periodontal disease and caries 3: COVID-19 testing using Saliva and Nasal swabs 4. Analyze and characterize the oral microbiome in the presence COVID-19 in the Saliva and Dental plaque samples 5. Understanding the association between buprenorphine and oral health outcomes 6. Advancing Salivary Biomarker Development and Utility in Periodontitis 7. Targeting Health Disparities: Engineering Antimicrobial and Remineralizing Dental Resins for Therapeutic and Preventive Care in Underserved Communities, Amendment, BSO, IBC-24-349 (v.85.0), 7/9/2026

Lucero, Diego, New Modulators of Lipoprotein Metabolism: From the liver to the vascular wall., Amendment, BSO, IBC-25-97 (v.48.0), 7/9/2026

Higashi, Richard M., Environmental Systems Biochemistry, Amendment, BSO, IBC-26-22 (v.18.0), 7/9/2026

D'Orazio, John, Culture and transfection of human cell lines, Amendment, BSO, IBC-26-32 (v.18.0), 7/7/2026

Stone, Austin, Randomized, Prospective, Double Blind, Multi-Center, Phase 3 Pivotal Clinical Trial to Compare Efficacy and Safety of CARTISTEM® and Surgical Comparator in Subjects with Knee Cartilage Lesions and Osteoarthritis, Amendment, BSO, IBC-25-186 (v.16.0), 7/7/2026

Staton, Michele, STOP Study, Amendment, BSO, IBC-25-155 (v.18.0), 7/7/2026

Dreaden, Tyler, B23-4296-M: Brown Spot Needle Blight Isolation/DNA Extraction, Renewal, BSO, IBC-26-64 (v.10.0), 7/2/2026

Helsley, Robert, Macronutrient metabolism in Cardiometabolic Disease, Amendment, BSO, IBC-25-78 (v.40.0), 7/2/2026

Protocols Meeting Registration Requirements

Protocols that have been approved by the IBC pending minor modifications that have met approval requirements.

Morgan, Melissa, General Operations of the Food Microbiology Laboratory (Renewal 2026), Renewal, IBC, IBC-26-47 (v.16.0), 8/11/2026

Helmy, Yosra, Evaluation of the efficacy of different antibiotic alternatives against infectious pathogens pathogens, Amendment, IBC, IBC-25-12 (v.47.0), 8/7/2026

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Selene, Insija, NCI-CIRB-S2419: Phase III Double-Blinded Trial of Immune-Based Therapy with a Live Biotherapeutic MO-03 or Placebo for Frontline Therapy of Advanced Clear Cell Renal Cell Carcinoma [BioFront Trial], New, IBC, IBC-26-71 (v.8.0), 7/30/2026

Farman, Mark, Clonal variation in expression as a mechanism of pathogenic variability in the rice blast fungus, Renewal, IBC, IBC-26-51 (v.11.0), 7/28/2026

Guo, Houfu, Structure and function studies of lysyl hydroxylases, Renewal, IBC, IBC-26-66 (v.12.0), 7/27/2026

Li, Feng, Influenza D Virus Entry and Tissue Tropism, Amendment, IBC, IBC-24-32 (v.48.0), 7/23/2026

Dutch, Rebecca, Paramyxovirus and pneumovirus protein function, Amendment, IBC, IBC-24-134 (v.34.0), 7/20/2026

Zhu, Hongyan, Genetic and molecular analysis of root-nodule symbiosis in legumes, Renewal, IBC, IBC-26-62 (v.10.0), 7/20/2026

Shaffer, Carrie, B23-4242-M: Molecular Mechanisms of Bacterial Secretion Systems, Renewal, IBC, IBC-26-69 (v.14.0), 7/17/2026

Tsyusko-Unrine, Olga, Toxicity of environmental contaminants, Renewal, IBC, IBC-26-60 (v.13.0), 7/16/2026

Barry-Hundeyin, Mautin, Study of immune tumor microenvironment in gastrointestinal cancers, Renewal, IBC, IBC-26-55 (v.12.0), 7/14/2026

Wise, Kiersten, B23-4305: Management of Corn, Sorghum and Forage Diseases, Amendment, IBC, IBC-24-129 (v.17.0), 7/14/2026

Liu, Xiaoqi, Plk1 in epigenetics of prostate cancer development and progression, Amendment, IBC, IBC-24-114 (v.65.0), 7/13/2026

Fry, Christopher, Cellular regulators of skeletal muscle plasticity, Amendment, IBC, IBC-25-74 (v.40.0), 7/10/2026

Martinez, Natalia, Burley and Dark Tobacco Disease Management, Renewal, IBC, IBC-26-50 (v.11.0), 7/9/2026

Santollo, Jessica, Estrogen Receptor Regulation of Fluid Intake, Renewal, IBC, IBC-26-56 (v.14.0), 7/8/2026

Li, Feng, Rotavirus Project, Amendment, IBC, IBC-24-388 (v.38.0), 7/8/2026

Beckmann, Joshua, Neurobehavioral mechanisms of conditioned reinforcers and relative reinforcer value, Renewal, IBC, IBC-26-53 (v.8.0), 7/6/2026

Beckmann, Joshua, Neurobehavioral mechanisms of conditioned reinforcers and relative reinforcer value, Renewal, IBC, IBC-26-53 (v.8.0), 7/6/2026

IBC Training

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None. All current IBC members have completed training online via SciShield.

Adjournment

Doug Harrison moved to adjourn the meeting at 1:51PM. Amelia Pinto seconded the motion. All members present (11) voted in favor.

APPROVED